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FEDERAL REGISTER

Vol. 81 Monday,
No. 89 May 9, 2016

Book 1 of 2 Books
Pages 27983–28160

OFFICE OF THE FEDERAL REGISTER

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The President

Proclamation 9441 of May 4, 2016

National Day of Prayer, 2016

By the President of the United States of America

A Proclamation

In times of steady calm and extraordinary change alike, Americans of all walks of life have long turned to prayer to seek refuge, demonstrate gratitude, and discover peace. Sustaining us through great uncertainty and moments of sorrow, prayer allows us an outlet for introspection, and for expressing our hopes, desires, and fears. It offers strength in the face of hardship, and redemption when we falter. Our country was founded on the idea of religious freedom, and we have long upheld the belief that how we pray and whether we pray are matters reserved for an individual's own conscience. On National Day of Prayer, we rededicate ourselves to extending this freedom to all people.

Every day, women and men use the wisdom gained from humble prayer to spread kindness and to make our world a better place. Faith communities at home and abroad have helped feed the hungry, heal the sick, and protect innocents from violence. Nurturing communities with love and understanding, their prayer inspires their work, which embodies a timeless notion that has kept humanity going through the ages—that one of our most sacred responsibilities is to give of ourselves in service to others.

The threats of poverty, violence, and war around the world are all too real. Our faith and our earnest prayers can be cures for the fear we feel as we confront these realities. Helping us resist despair, paralysis, or cynicism, prayer offers a powerful alternative to pessimism. Through prayer, we often gain the insight to learn from our mistakes, the motivation to always be better, and the courage to stand up for what is right, even when it is not popular.

Each of us is an author in our collective American story, and in participating in our national discourse to address some of our Nation's greatest challenges, we are reminded of the blessing we have to live in a land where we are able to freely express the beliefs we hold in our hearts. The United States will continue to stand up for those around the world who are subject to fear or violence because of their religion or beliefs. As a Nation free to practice our faith as we choose, we must remember those around the world who are not afforded this freedom, and we must recommit to building a society where all can enjoy this liberty and live their lives in peace and dignity.

On this day, may our faiths enable us to sow the seeds of progress in our ever-changing world. Let us resolve to guide our children and grandchildren to embrace freedom for all, to see God in everyone, and to remember that no matter what differences they may have, they, just like we, will always be united by their common humanity.

The Congress, by Public Law 100–307, as amended, has called on the President to issue each year a proclamation designating the first Thursday in May as a "National Day of Prayer."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 5, 2016, as

National Day of Prayer. I invite the citizens of our Nation to give thanks, in accordance with their own faiths and consciences, for our many freedoms and blessings, and I join all people of faith in asking for God's continued guidance, mercy, and protection as we seek a more just world.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–10952
Filed 5–6–16; 8:45 am]
Billing code 3295–F6–P

Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 52

[Document Number AMS–FV–14–0016, FV–16–326]

United States Standards for Grades of Canned Baked Beans

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final notice.

SUMMARY: This document revises the United States Standards for Grades of Canned Baked Beans. The U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS) revised the standards to replace process-specific language "Product Description" in the standard with language reflective of current canned baked bean manufacturing practices. Additionally, AMS separated the canned dried beans, canned pork and beans, and canned baked beans grade standards from one shared standard document into three separate documents. These revisions bring the grade standards for canned baked beans in line with the present quality levels being marketed today and provide guidance in the effective use of these products.

DATES: *Effective:* June 8, 2016.

FOR FURTHER INFORMATION CONTACT: Brian E. Griffin, Agricultural Marketing Specialist, Specialty Crops Inspection Division, Specialty Crops Program, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Room 1536, South Building; STOP 0240, Washington, DC 20250; telephone (202) 720–5021; fax (202) 690–1527; or, email *brian.griffin@ams.usda.gov.* Copies of the revised U.S. Standards for Grades of Canned Baked Beans are available on the Internet at *http:// www.regulations.gov* or *http:// www.ams.usda.gov/.*

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices."

AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The U.S. standards for grades of fruits and vegetables that are not connected with Federal marketing orders or U.S. import requirements no longer appear in the Code of Federal Regulations, but are maintained by USDA, AMS, Specialty Crops Program, and are available on the Internet at: *http://www.ams.usda.gov/.*

AMS revised the voluntary U.S. Standards for Grades of Canned Baked Beans using the procedures that appear in part 36 of Title 7 of the Code of Federal Regulations (7 CFR part 36).

Background

In September 2013, AMS received a petition from a professor emeritus in food science at Michigan State University asking the Agency to consider revising the current U.S. grade standards for canned baked beans to account for advances in industry processing technology. The petitioner requested the removal of the following text from the Product Description: "The product is prepared by washing, soaking, and baking by the application of dry heat in open or loosely covered containers in a closed oven at atmospheric pressure for sufficient prolonged time to produce a typical texture and flavor" and replacing it with: "The product is prepared by heating beans and sauce in a closed or open container for a period of time sufficient to provide texture, flavor, color, and consistency attributes that are typical for this product."

Additional proposed changes to the U.S. Standards for Grades of Canned Baked Beans included separating the shared standard for canned dried beans, canned pork and beans, and canned baked beans into three individual standard documents and make minor editorial changes. These grade standards are recognized as three individual standards, but are contained in one document.

AMS published a proposed notice in the **Federal Register** on August 19, 2015 (80 FR 50262) with a 60-day public comment period. AMS received one comment in favor of the proposed changes to the canned baked bean standards.

This notice announces revisions to the third issuance of the U.S. Standards for Grades of Canned Baked Beans, which became effective on September 1, 1976, as follows:

Product Description. The text for § 52.6461 Product Description is revised to be: "The product is prepared by washing, soaking, and baking beans and sauce through the application of heat in a closed or open container for a period of time sufficient to provide texture, flavor, color, and consistency attributes that are typical for this product."

Additionally, the U.S. Standards for Grades of Canned Dried Beans, Canned Pork and Beans, and Canned Baked Beans are separated into individual documents for the canned dried beans grade standards, canned pork and beans grade standards, and canned baked beans grade standards. There are no changes to the content of the canned dried beans or canned pork and beans grade standards.

The official grade of a lot of canned baked beans covered by these standards will be determined by the procedures set forth in the Regulations Governing Inspection and Certification of Processed Products, Thereof, and Certain Other Processed Food Products (7 CFR 52.1 to 52.83).

The revisions to the canned baked bean grade standard in this notice provide a common language for trade and better reflect the current marketing of canned baked beans. The changes are effective June 8, 2016.

Authority: 7 U.S.C. 1621–1627.

Dated: May 3, 2016.

Elanor Starmer,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2016–10743 Filed 5–6–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–4808; Directorate Identifier 2014–NM–134–AD; Amendment 39–18509; AD 2016–09–11]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200 and –300 series airplanes. This AD was prompted by reports that cracks were found on an adjacent hole of certain frames of the center wing box (CWB). This AD requires removing fasteners, doing a rototest inspection of fastener holes, installing new fasteners, oversizing the holes and doing rototest inspections for cracks if necessary, and repairing any cracking that is found. We are issuing this AD to detect and correct cracking on certain holes of certain frames of the CWB that could affect the structural integrity of the airplane.

DATES: This AD becomes effective June 13, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 13, 2016.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.* For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4808.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4808; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200 and –300 series airplanes. The NPRM published in the **Federal Register** on November 2, 2015 (80 FR 67348) (“the NPRM”). We are issuing this AD to detect and correct cracking on certain holes of certain frames of the CWB, which could affect the structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0149, dated June 13, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200 and –300 series airplanes. The MCAI states:

> During accomplishment of A330 Airworthiness Limitation Item (ALI) task 57–11–04 on the rear fitting of the Frame (FR) 40 between stringers 38 and 39 on both [left-hand] LH/[right-hand] RH sides, cracks were found on an adjacent hole. After reaming at second oversize of the subject hole, the crack was still present.
>
> Other crack findings on this adjacent hole have been reported on A330 and A340–200/300 aeroplanes as a result of sampling inspections.
>
> This condition, if not detected and corrected, could affect the structural integrity of the aeroplane.
>
> For the reasons described above, this [EASA] AD requires removal of the fasteners and repetitive rototest inspections of fastener holes at FR40 vertical web located above Center Wing Box (CWB) lower panel reference and/or below CWB lower panel reference on both sides and, depending on findings, accomplishment of the applicable corrective actions.
>
> **Note:** These holes affected by this [EASA] AD are different from the ones affected by EASA AD 2009–0001 [*http://ad.easa.europa.eu/blob/easa_ad_2009_0001.pdf/AD_2009-0001_1*].

Required actions also include oversizing certain holes, installing new fasteners, and repairing any cracking that is found. The initial compliance times range from 13,500 to 30,900 flight cycles, or 57,000 to 162,000 flight hours, depending on airplane operation and utilization. The repetitive compliance times are 7,400 flight cycles/24,300 flight hours or 5,950 flight cycles/40,400 flight hours from ALI embodiment. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4808.

Change Made to the Format of Paragraph (g) of This AD

At the request of the Office of the Federal Register, we have revised the format of paragraph (g) of this AD by converting the table to text. This change to the format does not affect the requirements of that paragraph.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received. The commenter, Bowen Gass, supported the NPRM.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information. The service information describes procedures for removing the fasteners and doing a repetitive rototest inspection of fastener holes at FR40 vertical web on both sides, installing new fasteners in transition fit, and oversizing the holes.

- Airbus Service Bulletin A330–57–3114, dated March 12, 2013.
- Airbus Service Bulletin A330–57–3115, dated April 4, 2013.

- Airbus Service Bulletin A330–57–3116, dated March 12, 2013.
- Airbus Service Bulletin A340–57–4123, dated March 12, 2013.
- Airbus Service Bulletin A340–57–4124, Revision 01, dated August 22, 2013.
- Airbus Service Bulletin A340–57–4125, dated March 12, 2013.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 35 airplanes of U.S. registry.

We also estimate that it will take about 78 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $0 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $232,050, per inspection cycle, or $6,630 per product, per inspection cycle.

In addition, we estimate that any necessary follow-on actions will take about 98 work-hours and require parts costing $136,400, for a cost of up to $144,730 per product. We have no way of determining the number of aircraft that might need this action.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–09–11 Airbus: Amendment 39–18509. Docket No. FAA–2015–4808; Directorate Identifier 2014–NM–134–AD.

(a) Effective Date

This AD becomes effective June 13, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category, all manufacturer serial numbers, except those on which Airbus Modification (Mod) 55792 or Mod 55306 has been embodied in production, and except those on which Airbus Repair Instruction R57115092 has been embodied in service on both right-hand (RH) and left-hand (LH) sides.

(1) Airbus Model A330–201, –202, –203, –223, –223F, –243 –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(2) Airbus Model A340–211, –212, –213, –311, –312, and –313 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by reports that cracks were found on an adjacent hole of certain frames of the center wing box (CWB). We are issuing this AD to detect and correct cracking on certain holes of the CWB, which could affect the structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection

Do a rototest inspection of the fastener holes at the frame (FR) 40 vertical web, on both sides, as specified in paragraphs (g)(1) through (g)(6) of this AD, except as required by paragraph (k) of this AD.

(1) For Model A330–300 series airplanes in pre-mod 44360 configuration: At the later of the times specified in paragraphs (g)(1)(i) and (g)(1)(ii) of this AD, inspect below the CWB lower panel reference, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–57–3114, dated March 12, 2013.

(i) At the applicable time specified in paragraph 1.E., "Compliance" of Airbus Service Bulletin A330–57–3114, dated March 12, 2013.

(ii) Within 2,400 flight cycles or 24 months after the effective date of this AD, whichever occurs first.

(2) For Model A330–200 series airplanes in post-mod 44360 and pre-mod 49202 configuration: At the later of the times specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD, inspect below the CWB lower panel reference, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–57–3116, dated March 12, 2013.

(i) At the applicable time specified in paragraph 1.E., "Compliance," of Airbus Service Bulletin A330–57–3116, dated March 12, 2013.

(ii) Within 2,400 flight cycles or 24 months after the effective date of this AD, whichever occurs first.

(3) For Model A330–200 and –300 series airplanes in pre-mod 55306 and pre-mod 55792 configuration: At the later of the times specified in paragraphs (g)(3)(i) and (g)(3)(ii) of this AD, inspect above the CWB lower panel reference, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–57–3115, dated April 4, 2013.

(i) At the applicable time specified in paragraph 1.E., "Compliance" of Airbus Service Bulletin A330–57–3115, dated April 4, 2013.

(ii) Within 2,400 flight cycles or 24 months after the effective date of this AD, whichever occurs first.

(4) For Model A340–200 and –300 series airplanes in pre-mod 44360 configuration: At the later of the times specified in paragraphs (g)(4)(i) and (g)(4)(ii) of this AD, inspect below the CWB lower panel reference, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A340–57–4123, dated March 12, 2013.

(i) At the applicable time specified in paragraph 1.E., "Compliance" of Airbus

Service Bulletin A330–57–4123, dated March 12, 2013.

(ii) Within 1,300 flight cycles or 24 months after the effective date of this AD, whichever occurs first.

(5) For Model A340–200 and –300 series airplanes in pre-mod 55306 and pre-mod 55792 configuration: At the later of the times specified in paragraphs (g)(5)(i) and (g)(5)(ii) of this AD, inspect above the CWB lower panel reference, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A340–57–4124, Revision 01, dated August 22, 2013.

(i) At the applicable time specified in paragraph 1.E., "Compliance," of Airbus Service Bulletin A340–57–4124, Revision 01, dated August 22, 2013.

(ii) Within 1,300 flight cycles or 24 months after the effective date of this AD, whichever occurs first.

(6) For Model A340–200 and –300 series airplanes in post-mod 44360 and pre-mod 49202 configuration: At the later of the times specified in paragraphs (g)(6)(i) and (g)(6)(ii) of this AD, inspect below the CWB lower panel reference, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A340–57–4125, dated March 12, 2013.

(i) At the applicable time specified in paragraph 1.E., "Compliance," of Airbus Service Bulletin A340–57–4125, dated March 12, 2013.

(ii) Within 1,300 flight cycles or 24 months after the effective date of this AD, whichever occurs first.

(h) Follow-on Actions: No Cracking

If no crack is found during any inspection required by paragraph (g) of this AD, do the actions specified in paragraphs (h)(1) and (h)(2) of this AD.

(1) Before further flight, install new fasteners in the transition fit, in accordance with the Accomplishment Instructions of the applicable service information identified in paragraph (g) of this AD.

(2) Repeat the inspection required by paragraph (g) of this AD thereafter at the applicable time identified in paragraph 1.E., "Compliance," of the applicable service information identified in paragraph (g) of this AD.

(i) Follow-on Actions for Crack Findings

If any crack is found during any inspection required by paragraph (g) of this AD: Before further flight, oversize the holes to the first oversize in comparison with the current hole diameter, and do a rototest inspection for cracks, in accordance with the Accomplishment Instructions of the applicable service information identified in paragraph (g) of this AD.

(1) If no cracking is found during the rototest inspection required by paragraph (i) of this AD, do the actions specified in paragraphs (i)(1)(i) and (i)(1)(ii) of this AD.

(i) Before further flight: Install new fasteners in the transition fit, in accordance with the Accomplishment Instructions of the applicable service information identified in paragraph (g) of this AD.

(ii) Repeat the inspection required by paragraph (g) of this AD thereafter at the applicable time identified in paragraph 1.E., "Compliance," of the applicable service information identified in paragraph (g) of this AD.

(2) If cracking is found during the rototest inspection required by paragraph (i) of this AD: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(j) Terminating Action Specifications

Accomplishment of the initial and repetitive inspections required by this AD terminates accomplishment of Airworthiness Limitation Items Tasks 57–11–04 and 57–11–02 of the Airworthiness Limitation Section (ALS) Part 2, Damage Tolerant Airworthiness Limitation Items (DT ALI).

(1) Installation of new fasteners, as specified in paragraph (h)(1) of this AD, does not terminate the repetitive inspections required by paragraph (g) of this AD.

(2) Accomplishment of the corrective actions specified in the introductory text of paragraph (i) and paragraph (i)(1) of this AD does not terminate the repetitive inspections required by paragraph (g) of this AD.

(3) Accomplishment of the repair specified in paragraph (i)(2) of this AD does not terminate repetitive inspections required by paragraph (g) of this AD, unless the approved repair method specifies otherwise.

(k) Exceptions to Service Information

(1) If the applicable service information identified in paragraph (g) of this AD specifies contacting Airbus for appropriate action: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA.

(2) Where paragraph 1.E., "Compliance," of the applicable service information specified in paragraph (g) of this AD specifies a compliance time in terms of a "Threshold" and "Grace Period," this AD requires compliance at the later of the applicable threshold and grace period.

(3) Where paragraph 1.E., "Compliance," of the applicable service information specified in paragraph (g) of this AD specifies a threshold as "before next flight," this AD requires compliance before the next flight after the applicable finding.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (i) of this AD, if those actions were performed before the effective date of this AD using the applicable service information specified in paragraph (l)(1), (l)(2), (l)(3), (l)(4), (l)(5), (l)(6), (l)(7), (l)(8), or (l)(9) of this AD. This service information is not incorporated by reference in this AD.

(1) Airbus Technical Disposition LR57D11023270, Issue B, dated July 12, 2011.

(2) Airbus Technical Disposition LR57D11029171, Issue B, dated September 6, 2011.

(3) Airbus Technical Disposition LR57D11029173, Issue B, dated September 6, 2011.

(4) Airbus Technical Disposition LR57D11030741, Issue B, dated September 22, 2011.

(5) Airbus Technical Disposition LR57D11029170, Issue C, dated September 6, 2011.

(6) Airbus Technical Disposition LR57D11023714, Issue B, dated July 12, 2011.

(7) Airbus Technical Disposition LR57D11029172, Issue B, dated September 6, 2011.

(8) Airbus Technical Disposition LR57D11030740, Issue C, dated September 22, 2011.

(9) Airbus Service Bulletin A340–57–4124, dated April 4, 2013.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0149, dated June 13, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4808.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (o)(4) of this AD.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Service Bulletin A330–57–3114, dated March 12, 2013.

(ii) Airbus Service Bulletin A330–57–3115, dated April 4, 2013.

(iii) Airbus Service Bulletin A330–57–3116, dated March 12, 2013.

(iv) Airbus Service Bulletin A340–57–4123, dated March 12, 2013.

(v) Airbus Service Bulletin A340–57–4124, Revision 01, dated August 22, 2013.

(vi) Airbus Service Bulletin A340–57–4125, dated March 12, 2013.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 21, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10287 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0246; Directorate Identifier 2014–NM–187–AD; Amendment 39–18511; AD 2016–09–13]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–300, –400, and –500 series airplanes. This AD was prompted by reports of fatigue cracking found at the left-side and right-side upper frames, at a certain area. This AD requires repetitive medium frequency eddy current (MFEC) inspections for cracking of the left-side and right-side upper frames, and repair (including open hole high frequency eddy current (HFEC) inspections for cracking of fastener holes) if necessary. This AD also provides an optional preventive modification, which terminates the repetitive inspections at the modified location. We are issuing this AD to detect and correct fatigue cracking of the upper frame, which can grow in size and result in a severed frame, leading to rapid decompression and consequent reduced structural integrity of the airplane.

DATES: This AD is effective June 13, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 13, 2016.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0264.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0246; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Galib Abumeri, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, California 90712–4137; phone: 562–627–5324; fax: 562–627–5210; email: *galib.abumeri@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on February 24, 2015 (80 FR 9667) (“the NPRM”). The NPRM was prompted by reports of fatigue cracking found at the left-side and right-side upper frame, at a certain area. The NPRM proposed to require repetitive MFEC inspections for cracking of the left-side and right-side upper frames, and repair (including open hole HFEC inspections for cracking of fastener holes) if necessary. The NPRM also provided an optional preventative modification that would terminate the repetitive inspections at the modified location. We are issuing this AD to detect and correct fatigue cracking of the upper frame, which can grow in size and result in a severed frame, leading to rapid decompression and consequent reduced structural integrity of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Requests To Clarify Compliance Time

Europe Airpost and Boeing requested that we revise the NPRM to clarify the “Condition” column of table 1 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, which specifies airplanes with certain flight cycles “on the original issue date of this service bulletin.” The commenters questioned whether the corresponding compliance time should be “on the effective date of the AD.”

For the reasons suggested by both commenters, we agree to add paragraph (i)(3) to this AD to state that the corresponding reference point is on the effective date of this AD, and we have included reference to paragraph (i)(3) in all appropriate paragraphs in this AD.

Request for Clarify Inspection Requirements

Boeing requested that we revise paragraph (g) of the proposed AD to address the inspection requirements in areas of an existing repair to eliminate cracking approved by a Boeing Organization Designation Authorization (ODA) via FAA Form 8100–9. Boeing explained that this condition is addressed in note (c) of table 1 of paragraph 1.E., “Compliance,” of Boeing

Alert Service Bulletin 737–53A1339, dated August 12, 2014, and that it effectively terminates the initial and repetitive inspections required by paragraph (g) of the proposed AD for previously installed frame repairs approved by the Boeing ODA via FAA Form 8100–9. Boeing requested that the proposed AD address the terminating action for this repair condition.

We agree that clarification is necessary. Boeing ODA-approved repairs installed prior to the effective date of this AD are acceptable to terminate the initial and repetitive inspections in the area under the repair. We have revised paragraph (g) of this AD accordingly, and added a new paragraph (g)(1) in this AD.

Request To Clarify Required for Compliance (RC) Requirements

Southwest Airlines requested that we clarify paragraph (l)(4) of the proposed AD. Southwest Airlines explained that note 15 in paragraph 3.A., "General Information," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, states that steps in the Work Instructions that are identified as RC must be accomplished once the actions specified in Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, becomes mandated by an AD. Southwest Airlines stated that note 15 also states that deviations to steps that are not identified as RC do not require approval of an Alternative Method of Compliance (AMOC). Southwest Airlines stated that paragraph (l)(4) of the proposed AD specifies that any service information that is identified as RC requires AMOC approval except as required by paragraph (i)(1) of the proposed AD. Paragraph (k) of the proposed AD states that the post-repair and post-modification inspections are not mandated by the AD, so it is unclear whether the proposed AD would require the operator to contact Boeing if there are crack findings during the post-repair and post-modification inspections, and whether or not the resulting repairs are subject to the requirements of the AD.

We agree to provide clarification. Paragraph (k) of this AD states that the post-repair and post-modification inspections specified in tables 4 and 5 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, are not required by this AD (tables 4 and 5 correspond to Parts 6 and 7, respectively, of the service information.). The RC steps in those parts are also not required by this AD. Any cracking found—whether during accomplishment of the actions required by an AD or during routine maintenance—is required by 14 CFR 43.13(b) to be repaired before further flight. However, for clarity, we have revised paragraph (i)(1) of this AD to refer only to Part 3 and Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014. In addition, we have revised paragraph (l)(4) of this AD to refer to Part 2, Part 3, and Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014.

Request To Address Repairs for Damage Other Than Cracking

Southwest Airlines stated that the NPRM does not specifically address existing repairs that prevent accomplishment of the inspections proposed in paragraph (g) of the proposed AD. Note (c) in table 1 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, specifies that an ODA-approved repair, via FAA Form 8100–9, installed to eliminate previously found cracking, eliminates the need for the repetitive inspections at the repaired locations. Southwest requested that we revise the NPRM to apply this provision to repairs for damage other than cracking. Southwest Airlines also requested that we specifically state that any repair approved by Boeing via an FAA 8100–9 combined with approval of an AMOC to paragraph (h) of the proposed AD terminates both the initial and repetitive inspections required by paragraph (g) of the proposed AD.

We agree to add clarification regarding initial and repetitive inspections. To provide additional clarification in the rule we have revised the wording in paragraphs (g) and (h) of this AD. Also, we agree to revise the NPRM to include in this final rule, the provision for repairs for cracking in paragraph (g)(1) of this AD, and the provision for repairs that were installed for damage other than cracking that have been re-evaluated and approved by the Boeing ODA with an FAA Form 8100–9 combined with an AMOC statement, in paragraph (g)(2) of this AD.

Effect of Winglets on the Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf*) does not affect the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) in this AD, and have added new paragraph (c)(2) to this AD to state that installation of STC ST01219SE does not affect the ability to accomplish the actions required by this final rule. Therefore, for airplanes on which STC ST01219SE is installed, a "change in product" AMOC approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Change to Paragraph (k) of This AD

We have revised paragraph (k) of this AD to clarify that the post-modification inspections are airworthiness limitations that are required by maintenance and operational rules; therefore, these inspections are not required by this AD.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Boeing has issued Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014. The service information describes procedures for repetitive MFEC inspections for cracking, repair the cracking including doing an open hole HFEC inspections for cracking of the holes, and an optional modification of an inspection area including open hole and surface HFEC inspections for cracking of the area to be modified. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 109 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	14 work-hours × $85 per hour = $1,190 per inspection cycle.	$0	$1,190 per inspection cycle.	$129,710 per inspection cycle.
Preventive modification (optional).	15 work-hours × $85 per hour = $1,275	0	$1,275	$138,975.

We estimate the following costs to do any necessary on-condition actions that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair and open hole HFEC inspection	36 work-hours × $85 per hour = $3,060	$0	$3,060

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–09–13 The Boeing Company: Amendment 39–18511; Docket No. FAA–2015–0246; Directorate Identifier 2014–NM–187–AD.

(a) Effective Date

This AD is effective June 13, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53: Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of fatigue cracking found at the left-side and right-side upper frames, at station 360 between stringer 13 and stringer 14. We are issuing this AD to detect and correct fatigue cracking of the upper frame, which can grow in size and result in a severed frame, leading to rapid decompression and consequent reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections for Cracking

Except as required by paragraphs (i)(2) and (i)(3) of this AD: At the applicable times specified in table 1 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, do a medium frequency eddy current (MFEC) inspection for cracking on the left-side and right-side of the upper frame at station 360 between stringer 13 and stringer 14, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014. If no cracking is found, repeat the inspections at the applicable times specified in table 1 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014. Accomplishment of the actions specified in paragraph (j) of this AD terminates the repetitive inspections required by this paragraph at the modified area only. The initial and repetitive inspections required by this paragraph may be terminated in the area under repairs installed prior to the effective date of this AD, provided they meet the requirements of paragraph (g)(1) or (g)(2) of this AD.

(1) Repairs were installed to eliminate previously found cracking and were

approved by the Boeing Organization Designation Authorization (ODA) with an FAA Form 8100–9.

(2) Repairs were installed for damage other than cracking that have been re-evaluated and approved by the Boeing ODA with an FAA Form 8100–9 that includes an alternative method of compliance (AMOC) statement to paragraph (h) of this AD.

(h) Repair

If any cracking is found during any inspection required by paragraph (g) of this AD: Before further flight, repair the cracking including doing an open hole high frequency eddy current (HFEC) inspection for cracking of the holes, in accordance with Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, except as required by paragraph (i)(1) of this AD. Repair of any crack terminates the initial and repetitive inspection requirements of paragraph (g) of this AD for the repaired area only. If any cracking is found during any inspection required by this paragraph, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(i) Exceptions to Service Information Specifications

(1) Where Part 3 and Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, specifies contacting Boeing for repair instructions: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(2) Where Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, specifies a compliance time "after the original issue date of this service bulletin," this AD requires compliance within the specified time after the effective date of this AD.

(3) Where the Condition column of table 1 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, specifies a reference point "on the original issue date of this service bulletin," for this AD the corresponding reference point is on the effective date of this AD.

(j) Optional Preventive Modification

Modification of an inspection area specified in paragraph (g) of this AD, including open hole and surface HFEC inspections for cracking of the area to be modified, in accordance with Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, except as required by paragraph (i)(1) of this AD, terminates the repetitive inspections required by paragraph (g) of this AD at the modified location only.

(k) Post-Repair and Post-Modification Inspections

Tables 4 and 5 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, specify post-modification airworthiness limitation inspections in compliance to 14 CFR 25.571(a)(3) at the modified locations, which support compliance with 14 CFR 121.1109(c)(2) or 129.109(b)(2). As airworthiness limitations, these inspections are required by maintenance and operational rules. It is therefore unnecessary to mandate them in this AD. Deviations from these inspections require FAA approval, but do not require an alternative method of compliance.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-REQUESTS@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by Boeing Commercial Airplanes ODA that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (i)(1) of this AD: Where Part 2, Part 3, and Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014, contains steps that are labeled as RC, the provisions of paragraphs (l)(4)(i) and (l)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(m) Related Information

For more information about this AD, contact Galib Abumeri, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, California 90712–4137; phone: 562–627–5324; fax: 562–627–5210; email: *galib.abumeri@faa.gov.*

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737–53A1339, dated August 12, 2014.

(ii) Reserved.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 28, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10524 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 97 and 160

46 CFR Part 97

[Docket No. USCG–2000–7080]

RIN 1625–AA25 [Formerly RIN 2115–AF97]

Cargo Securing Manuals

AGENCY: Coast Guard, DHS.

ACTION: Interim rule and request for comment.

SUMMARY: The Coast Guard is issuing an interim rule to require U.S. and foreign self-propelled cargo vessels of 500 gross tons or more, traveling on international voyages and carrying cargo that is other than solid or liquid bulk cargo, to have cargo securing manuals (CSMs) on board. The rule also requires those vessels to comply with certain provisions of the International Convention for the Safety of Life at Sea, 1974 as amended (SOLAS), authorizes recognized classification societies or other approval authorities to review and approve CSMs on behalf of the Coast Guard; and prescribes when and how

the loss or jettisoning of cargo at sea must be reported.

The Coast Guard requests public comment on its intention to extend, in a subsequent final rule, this interim rule's requirement for vessel CSMs to self-propelled cargo vessels under 500 gross tons, if these vessels carry dangerous goods in packaged form on international voyages. This interim rule promotes the Coast Guard's maritime safety and stewardship (environmental protection) missions, helps fulfill U.S. treaty obligations, and could help prevent or mitigate the consequences of vessel cargo loss.

DATES: This interim rule is effective June 8, 2016. Comments must be received by August 8, 2016. The incorporation by reference of certain documents in this rule is approved by the Director of the Federal Register as of June 8, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2000–7080 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Mr. Ken Smith, Project Manager, U.S. Coast Guard Headquarters, Vessel and Facility Operating Standards Division, Commandant (CG–OES–2); telephone 202–372–1413, email *Ken.A.Smith@uscg.mil.*

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

We are not planning to hold a public meeting but will consider doing so if public comments indicate a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

ABS	American Bureau of Shipping
BLS	U.S. Bureau of Labor Statistics
CFR	Code of Federal Regulations
CSAP	Cargo Safe Access Plan
CSM	Cargo Securing Manual
CSS Code	Code of Safe Practice for Cargo Stowage and Securing
E.O.	Executive Order
FR	Federal Register
FRFA	Final Regulatory Flexibility Analysis
IMO	International Maritime Organization
IRFA	Initial Regulatory Flexibility Analysis
MARAD	U.S. Department of Transportation's Maritime Administration
MBARI	Monterey Bay Aquarium Research Institute
MSC	Maritime Safety Committee
MISLE	Marine Information for Safety and Law Enforcement
NAICS	North American Industry Classification System
NPRM	Notice of Proposed Rulemaking
NVIC	Navigation and Vessel Inspection Circular
OMB	Office of Management and Budget
RFA	Regulatory Flexibility Act of 1980
§	Section Symbol
SANS	Ship Arrival Notification System
SBA	Small Business Administration
SNPRM	Supplemental Notice of Proposed Rulemaking
SOLAS	International Convention for the Safety of Life at Sea, 1974 as amended
U.S.C.	United States Code
WSC	World Shipping Council

III. Basis and Purpose

Sections 2103 and 3306 of Title 46, United States Code (U.S.C.), provide the statutory basis for this rulemaking. Section 2103 gives the Secretary of the department in which the Coast Guard is operating general regulatory authority to implement Subtitle II (Chapters 21 through 147) of Title 46, which includes statutory requirements in 46 U.S.C. Chapter 33 for inspecting the vessels to which this rulemaking applies. Section 3306 gives the Secretary authority to regulate an inspected vessel's operation, fittings, equipment, appliances, and other items in the interest of safety. The Secretary's authority under both statutes has been delegated to the Coast Guard in DHS Delegation No. 0170.1, para. II (92.a) and (92.b).

The purpose of this rule is to align Coast Guard regulations with the requirements for cargo securing manuals in the International Convention for the Safety of Life at Sea, 1974 as amended (SOLAS), and apply those requirements to certain self-propelled U.S. cargo vessels operating anywhere in the world, and to certain foreign-flagged self-propelled cargo vessels operating in U.S. waters. Another purpose of this rule is to specify when and how the loss or jettisoning of cargo at sea must be reported.

IV. Background and Regulatory History

This rule aims to help ensure that maritime cargo is properly secured. A recent survey by the World Shipping Council (WSC) estimated that an average of 1,679 containers are lost overboard annually.[1] The number of damaged and lost containers has risen over the years due to the increased traffic in containerized cargo and the increasing size of containerships.

Several incidents since the early 1990s demonstrated that improperly secured cargo can cause serious injury or death, vessel loss, property damage, and environmental damage. For example, a Coast Guard board of inquiry concluded that the loss of 21 containers—4 of which contained toxic arsenic trioxide—off the coast of New Jersey in 1992 was caused by cargo-securing failures, bad weather, and human error.[2] With the support of other International Maritime Organization (IMO) member governments, the United States led a proposal to include new requirements for cargo securing manuals (CSMs) in SOLAS. In 1994, the IMO amended SOLAS[3] to provide that, after 1997, vessels of 500 gross tons or more engaged in international trade and carrying cargo other than solid or liquid bulk material must carry a flag state-approved CSM; load, stow, and secure cargo in compliance with the CSM; and meet strength requirements for securing devices and arrangements.

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[1] Survey report is on WSC Web site: *http://www.worldshipping.org/industry-issues/safety/Containers_Lost_at_Sea_-_2014_Update_Final_for_Dist.pdf.*

The SOLAS CSM requirements are included as an annex to a Coast Guard guidance document issued in 1997,[4] but a vessel owner or operator's compliance with that guidance is only voluntary. This interim rule makes compliance with the SOLAS standards mandatory for self-propelled vessels over 500 gross tons on international voyages that are subject to SOLAS.

Previously in this rulemaking, we issued a notice of proposed rulemaking (NPRM)[5] in 2000 and a supplemental notice of proposed rulemaking (SNPRM)[6] in 2013. Although it was not part of this rulemaking, in 1999 we held a public meeting on topics related to cargo securing.[7] In the SNPRM, we discussed the comments we received on the 2000 NPRM and public input from the 1999 meeting. We discuss the comments we received on the 2013 SNPRM later in this preamble.

V. Summary of the Rule

This section summarizes the changes made in this interim rule.

33 CFR part 97—Rules for the Safe Operation of Vessels, Stowage and Securing of Cargoes. The interim rule adds this part, which is structured to allow for future regulations covering other aspects of vessel operation and cargo stowage and securing. At this time, the part contains only subpart A, which deals with CSMs.

Section 97.100 contains the applicability provisions of subpart A and provides for electronic submission of any documents required by the part. Subpart A applies to self-propelled cargo vessels of 500 gross tons or more traveling on international voyages and carrying any cargo other than solid or liquid bulk cargo. We expect very few vessels to be affected by the new requirements, as most foreign vessels operating in U.S. waters are already subject to their flag state's SOLAS CSM-aligned requirements, and all U.S. vessels already voluntarily comply with those requirements in order to obtain SOLAS certificates that are necessary for entering foreign ports. Subpart A also applies to self-propelled vessels less than 500 gross tons if their owners or operators choose voluntarily to have it apply to them and submit CSMs for approval.

We have revised the text of § 97.100 as it appeared in the SNPRM by removing seagoing barges and other non-self propelled vessels from the applicability of subpart A, which were inadvertently included in the proposed regulatory text of the SNPRM. This interim rule applies only to self-propelled cargo vessels that are subject to SOLAS Chapter VI/5.6 or Chapter VII/5.

As we discussed in Part V, Discussion of Comments, in our SNPRM, a commenter suggested extending the applicability of subpart A to self-propelled cargo vessels below 500 gross tons carrying dangerous goods in packaged form on international voyages. We agree with the commenter's assessment that the cargo securing manual requirements of Chapter VII/5 of SOLAS apply to all vessels covered by other SOLAS provisions *and* to vessels below 500 gross tons that carry dangerous goods in packaged form. As previously stated, one of our intentions in this rule is to align our regulations with SOLAS requirements for cargo securing manuals, and therefore we propose modifying the final rule to more accurately align with SOLAS by applying it to self-propelled cargo vessels less than 500 gross tons carrying dangerous goods in packaged form on international voyages, as well as to larger vessels. We specifically request public comment on that proposed change.

Section 97.105 defines terms used in subpart A, and § 97.110 provides for the incorporation in subpart A, by reference, of pertinent IMO circulars describing how vessels may comply with the SOLAS CSM requirements, as well as an IMO resolution providing guidelines for third parties acting on behalf of a government agency like the Coast Guard.

Section 97.115 requires any accidental loss or deliberate jettisoning of a container or other cargo at sea to be reported immediately under 33 CFR 160.215. This is because any such loss or jettisoning creates a "hazardous condition" within the meaning of 33 CFR 160.204. The section also requires the loss or jettisoning of cargo containing hazardous material to be reported as soon as possible in accordance with the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration regulations at 49 CFR 176.48.

Section 97.120 requires each vessel to which subpart A applies to have a flag state-approved CSM that complies with applicable IMO resolutions. Coast Guard personnel may board any vessel in U.S. waters to verify compliance with this section. Note that any container vessel with a keel laid on or after January 1, 2015, needs to include a cargo safe access plan. Under the applicable IMO guidance, such a plan must provide detailed information on safe access for persons stowing and securing cargo on vessels that are specifically designed and fitted for carrying containers.

Section 97.200 describes how a U.S.-flagged vessel owner or operator applies for Coast Guard approval of the vessel's CSM. Third-party approval authorities review and approve CSMs on the Coast Guard's behalf. This section also describes the contents of approval statements, the procedure to follow when a CSM is disapproved, and document retention requirements.

Section 97.205 describes when a CSM must be resubmitted for approval, and § 97.210 contains provisions for appeal from a CSM approval authority's decision.

Section 97.300 designates the organizations that are initially authorized to act as CSM approval authorities, and §§ 97.305 through 97.315 discuss who may request that authorization in the future, the criteria for authorization, and the requirements for approval authorities. We modified this section from what we originally published in the SNPRM by removing specific reference to the American Bureau of Shipping (ABS) and Lloyd's Register, because they are already included on the list of recognized classification societies to which the Coast Guard has delegated authority for the issuance of a Cargo Ship Safety Equipment Certificate in accordance with 46 CFR 8.320(b)(4) and covered under the paragraph recognizing those classification societies. Section 97.320 provides for the revocation of authorization if an approval authority fails to maintain standards acceptable to the Coast Guard.

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[2] *See* NVIC 10–97 (Nov. 7, 1997), "Guidelines for Cargo Securing Manual Approval," available at *http://www.uscg.mil/hq/cg5/nvic/pdf/1997/n10-97.pdf.*

[3] See SOLAS, Ch. VI/5.6 and Ch. VII/5.

[4] NVIC 10–97.

[5] 65 FR 75201 (Dec. 1, 2000).

[6] 78 FR 68784 (Nov. 15, 2013). Although not part of this rulemaking, in 1999 we announced (64 FR 1648; Jan. 11, 1999, docket USCG–1998–4951) and held a public meeting on related topics. Comments received at that meeting were discussed in the SNPRM, 78 FR at 68786, col. 2.

[7] 64 FR 1648 (Jan. 11, 1999); docket USCG–1998–4951.

33 CFR part 160—Ports and Waterways Safety—General. The only change made to part 160 is an amendment to § 160.215, to prescribe the information to be reported when a hazardous condition is created by the loss or jettisoning of cargo.

46 CFR part 97—[Cargo and Miscellaneous Vessel] Operations. The interim rule amends the subpart 97.12 operational rules for vessels carrying bulk solid cargoes by adding § 97.12–10, which requires such vessels to have on board a CSM that complies with 33 CFR part 97.

VI. Discussion of Comments on SNPRM and Changes

The SNPRM drew public comments from 12 sources: 7 Individuals (one of whom submitted 2 comments, which we consider together), 2 barge companies, 1 shipping industry organization, 1 trade association, and 1 environmental advocacy organization. The docket also contains 1 comment from another Federal agency.

General. All three organizations and six individuals expressed support for the Coast Guard's proposal.

The environmental advocacy organization and two individuals said that the loss of cargo containers is a serious problem. The organization said container loss has an immediate impact by changing deep sea habitats, and a long term impact by changing the natural distribution of species, including the threat of introducing invasive species. One individual said container loss is a major threat to the environment, to pleasure craft, and to commercial shipping. This commenter suggested that the insurance industry should welcome our proposal because of the economic impact of container losses. The other individual said we should require containers to be weighed so that weight can be distributed for safety.

We share these commenters' concern for the safety and environmental hazards that can be caused by the loss of containers or other cargo at sea, and we agree with most of their comments. However, we decline to require containers to be weighed, because this information is the subject of several existing Federal and International Maritime Organization (IMO) requirements. The Occupational Safety and Health Administration requires a container to be weighed before it can be handled by U.S. workers, and the Department of Transportation has stringent notification and certification requirements for intermodal containers.[8] With the Coast Guard's full participation, the IMO recently amended an international convention to require shippers to verify a container's gross mass to a vessel's master before it is loaded on board.[9] The existence of these requirements makes it unnecessary for the Coast Guard to issue separate and potentially overlapping provisions on the topic.

The shipping organization said that, whereas the SNPRM based its cost analysis on an IMO estimate of 4,000 containers lost at sea per year worldwide, the shipping organization's own analysis found that, on average, only 1,679 containers are lost at sea each year. We appreciate the shipping organization's analysis and are using their most current estimate in the regulatory analysis for this interim rule. Please see Section VIII, Regulatory Analyses, for details.

The two towing companies expressed appreciation that we do not propose to regulate cargo securing on barges in coastwise trade, but opposed our SNPRM's proposed extension[10] of such regulations to seagoing barges in international commerce. The companies said that barges have a strong safety record and are not subject to cargo securing requirements under SOLAS. Therefore, they should not be required to undertake the work of developing unique CSMs for each type of cargo. They also pointed out that, if seagoing barges are included, the universe of affected vessels will be far greater than the 26 U.S.-flagged vessels the Coast Guard estimates will be impacted in its regulatory analysis. They specifically requested that the Coast Guard clarify that "barges on international voyages will also be exempt from this rulemaking." We agree with the commenters and the interim rule amends the applicability provisions of new 33 CFR 97.100 so that part 97, subpart A, applies only to self-propelled vessels that are subject to SOLAS Chapter VI/5.6 or Chapter VII/5. SOLAS does not apply to non self-propelled vessels and the barge industry has demonstrated a strong safety record in the past. Therefore, we do not intend to require non-self-propelled vessels to have CSMs at this time.

Proposed change for final rule. One of the individual commenters said that, to conform to Chapter VII/5 of SOLAS, we should regulate cargo securing on cargo vessels below 500 gross tons as well as on vessels of 500 gross tons and above. We agree with the commenter's assessment that the cargo securing manual requirements of Chapter VII/5 of SOLAS apply to all vessels covered by other SOLAS provisions *and* to vessels below 500 gross tons that carry dangerous goods in packaged form. As previously stated, one of our intentions in this rule is to align our regulations with SOLAS requirements for cargo securing manuals, and, therefore, we propose modifying the final rule to more accurately align with SOLAS by extending the applicability provisions of 33 CFR 97.100 to self-propelled cargo vessels less than 500 gross tons carrying dangerous goods in packaged form on international voyages. We specifically request public comment on that proposal.

VII. Incorporation by Reference

The Director of the Federal Register has approved the material in 33 CFR 97.110 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. Copies of the material are available from the sources listed in § 97.110. The following paragraphs summarize the material incorporated by reference.

IMO Assembly Resolution A.739(18) (Res.A.739(18)), Guidelines for the Authorization of Organizations Acting on Behalf of the Administration, November 22, 1993: International guidelines developed to establish a uniform program for controlling and assigning authority of organizations to act on behalf of administrations in conducting surveys, certifications, and determination of tonnages.

IMO Maritime Safety Committee Circular 1352 (MSC.1/Circ.1352), Amendments to the Code of Safe Practice for Cargo Stowage and Securing (CSS Code) Annex 14, Guidance on Providing Safe Working Conditions for Securing of Containers on Deck, June 30, 2010: International guidance developed to ensure persons engaged in carrying out container securing operations on deck have safe working conditions including safe access, and appropriate securing equipment.

IMO Maritime Safety Committee Circular 1353 (MSC.1/Circ. 1353/Rev.1), Revised Guidelines for the Preparation of the Cargo Securing Manual, December 15, 2014: International guidelines providing information on developing cargo securing manuals, including required contents and details for stowing and securing non-standardized and semi-standardized cargo.

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[8] *See* 29 CFR 1918.85 and 49 U.S.C. 5902 for the Occupational Safety and Health Administration and Department of Transportation requirements, respectively.

[9] The International Convention for the Safety of Life at Sea, 1974, and its Protocol of 1988. *See* Regulation VI/2, which enters into force July 1, 2016. The International Maritime Organization previously issued guidance to help ensure accurate pre-loading container weighing; *see* Maritime Safety Committee Circular MSC.1/Circ. 1475, Guidelines Regarding the Verified Gross Mass of a Container Carrying Cargo.

[10] 78 FR at 68788, col. 1.

VIII. Regulatory Analyses

We developed this interim rule after considering numerous statutes and Executive Orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes or E.O.s.

A. Regulatory Planning and Review

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review, direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This rule has not been designated a "significant regulatory action" under section 3(f) of E.O. 12866, Regulatory Planning and Review, as supplemented by E.O. 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that E.O. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB). A final Regulatory Assessment for the interim rule follows.

1. Summary

This interim rule amends the CFR by adding the following provisions:

- Requirements for the reporting of lost or jettisoned cargo;
- The CSM requirements of SOLAS, for vessels of 500 gross tons or more;
- Extending the CSM requirements to self-propelled cargo vessels that travel on international voyages and carry cargo other than solid or liquid bulk cargo that is designated as a dangerous good carried in packaged form; and
- Procedures for authorization of third-party organizations to review and approve CSMs on the Coast Guard's behalf.

Table 1 presents a summary of our analysis.

TABLE 1—SUMMARY OF THE 10-YEAR REGULATORY ECONOMIC IMPACTS

Changes	Description	Affected population	Costs (7% discount rate)		Benefits
			Annualized	Total	
1. Reporting of lost or jettisoned cargo.	Codify lost or jettisoned cargo as a hazardous condition and specify data to be reported.	U.S.- and foreign-flagged vessels engaged in transport to or from a U.S. port.	$578	$4,063	Better tracking and response of lost or jettisoned cargo.
2. CSM requirements	Codify SOLAS rules and guidance from NVIC 10–97.	Owners/operators of 6,436 vessels: 83 U.S.-flagged, 6,353 foreign-flagged.	212,226	1,490,587	Increased enforcement authority.
3. Approval of authorized organizations.	Codify guidance from NVIC 10–97.	6 currently approved organizations, others applying for approval status.	0	0	Increased enforcement authority.
Total	....	....	212,804	1,494,649	

Note: Due to independent rounding, the totals may not equal the sum of the components.

Table 2 presents a summary of the 10-year cost schedule, showing total costs on an undiscounted basis and discounted at 7-percent and 3-percent interest rates.

TABLE 2—SUMMARY OF THE 10-YEAR TOTAL COST TO THE INTERNATIONAL CARGO INDUSTRY AND U.S. GOVERNMENT

Year	Undiscounted			Discounted	
	Industry	Government	Total	7%	3%
1	$757,015	$90,514	$847,529	$792,083	$822,844
2	99,403	10,013	109,416	95,568	103,135
3	99,417	10,023	109,440	89,336	100,153
4	99,430	10,034	109,464	83,510	97,257
5	107,068	10,044	117,112	83,499	101,022
6	107,081	10,055	117,136	78,053	98,100
7	107,108	10,076	117,184	72,976	95,281
8	107,121	10,086	117,207	68,216	92,524
9	114,759	10,097	124,856	67,913	95,692
10	114,786	10,118	124,904	63,495	92,940
Total	1,713,188	181,060	1,894,248	1,494,649	1,698,948
Annualized	....	....	....	212,804	199,169

2. Changes From SNPRM

Because there are no changes between the requirements proposed in the SNPRM and those contained in this interim rule, and because we received no public comments that affect the Regulatory Assessment, we retained the structure of the economic analyses from the SNPRM, but updated our analysis with the most current data. The data elements that we revised for this analysis are as follows:

- Affected vessel population, U.S.- and foreign-flagged vessels used 2011 through 2013 data.
- Visits to U.S. ports, updated with data from 2011 through 2013.
- Wage rates for commercial and Coast Guard employees, updated with current data.
- Container ship traffic data, updated with current data.

3. Affected Population

The affected population, those vessels subject to the regulations in this interim rule, consists of U.S.- and foreign-flagged self-propelled vessels that—

- Are engaged in international trade as indicated by currently having a SOLAS Cargo Ship Safety Certificate;
- Are 500 gross tons or more; and
- Carry any cargo other than solid or liquid bulk commodities.

The United States is a signatory state to SOLAS, and U.S.-flagged vessels in international trade must meet SOLAS requirements, including the CSM rules, to receive a SOLAS certificate. A 2013 extract from the Coast Guard's Marine Information for Safety and Law Enforcement (MISLE) database identified 83 U.S.-flagged vessels as meeting the above tonnage and cargo criteria.

The applicable foreign-flagged vessels are those that transit U.S. waters. The source for data on these vessels was the Coast Guard's Ship Arrival Notification System (SANS) database. This database contains data on notifications of arrival and departure of vessels to and from U.S. ports and is supplemented by data from MISLE. We extracted from SANS the most recent 3 years of data available, 2011 through 2013. This data produced a list of 6,353 foreign-flagged vessels that had one or more visits to a U.S. port and met the tonnage and cargo-type criteria. Table 3 presents the affected population of 6,436 vessels categorized by flag status, SOLAS status, and tonnage class (less than 500 gross tons, 500 gross tons or more).

TABLE 3—APPLICABLE POPULATION, NON-BULK CARGO VESSELS

Flag class	SOLAS status	Tonnage class in gross tons	Vessels	
U.S.	SOLAS	500 gross tons or more		83
Foreign	SOLAS	500 gross tons or more	6,314	
	Non-SOLAS	500 gross tons or more	39	
	Foreign Total		6,353	
Total				6,436

Notes:
(1) All U.S. vessels are SOLAS and in the 500 GT or more class.
(2) Foreign-flagged vessels will follow SOLAS CSM rules.

4. Economic Analyses

The economic analyses include—

- An analysis of the costs, benefits, and alternatives for each of the interim rule's three provisions: (a) Requirements for the reporting of lost or jettisoned cargo, (b) CSM requirements, and (c) Approval of authorized organizations. A summary of the costs and benefits for the entire rule; and
- A preliminary analysis of expanding the affected population.

a. Requirements for the reporting of lost or jettisoned cargo.

i. Current practices, applicable population, and description of changes and edits. As noted in Section IV, Background and Regulatory History, of this preamble, the current regulations require the Coast Guard to be notified immediately when a hazardous condition is caused by a vessel or its operation. Incidents of lost or jettisoned cargo [11] are considered hazardous conditions and must be reported. However, current industry practice does not correspond with that interpretation. According to Captain James J. McNamara, President of the National Cargo Bureau in 2000, "When a container or containers are lost overboard, usually there is no news release and seldom is the fact publicized. The loss is only revealed to those in a need-to-know situation, *i.e.,* the ship owner, shipper, receiver, and insurer." [12] As we will discuss in detail, our research indicates a significant underreporting of lost or jettisoned cargo to the Coast Guard. Coast Guard and other vessels cannot respond to these unreported incidents, so they represent a risk to navigation and the marine environment. The underreporting also prevents the Coast Guard and other interested parties from accurately tracking the extent and trends of lost cargo incidents.

In this interim rule we include requirements for the immediate reporting of lost or jettisoned cargo. We anticipate that adoption of these requirements will correct this underreporting and lead to some increased costs to industry. Table 4 presents the change matrix for modifying the reporting of hazardous conditions and summarizes the specific edit or change, the affected population, and the economic impact.

TABLE 4—CHANGE MATRIX FOR REPORTING OF HAZARDOUS CONDITIONS IN 33 CFR

Reference and description	Affected population	Economic impact
97.100 Applicability: . . . (a)(1), U.S. vessels	U.S. cargo vessels and non-U.S. cargo vessels in U.S. waters.	None, administrative only.

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[11] All data and industry reports refer only to containers when describing incidents involving lost or jettisoned cargo. We will assume that containers will continue as the only lost cargo in the future and refer to containers as the generic description of the involved cargo for this analysis.

[12] McNamara, James J., "Containers and Cargoes Lost Overboard," National Cargo Bureau; conference of the International Union of Marine Insurers; September 13, 2000, *http://www.iumi.com/images/stories/IUMI/Pictures/Conferences/London2000/Wednesday/02%20mcnamara%20cargo.pdf.*

TABLE 4—CHANGE MATRIX FOR REPORTING OF HAZARDOUS CONDITIONS IN 33 CFR—Continued

Reference and description	Affected population	Economic impact
97.105 Definitions	All vessels and approval organizations	None, administrative only.
97.110 Incorporation by reference, lists IBR references.	All affected vessels and approval organizations.	None, administrative only.
97.115 Situation requiring report, criteria for reporting lost cargo.	Vessels subject to the rule that lose cargo overboard.	Costs for correction of noncompliance with existing requirements.
160.215(a), requirement to report hazardous condition.	Operators of vessels involved in incident resulting in hazardous condition.	No change, new label of existing text.
160.215(b), data to be reported	Operators of vessels involved in incident resulting in hazardous condition.	This requirement references 97.115 and all costs are included there.

Source: Coast Guard analysis.

ii. Affected population. This interim rule applies to both U.S.- and foreign-flagged vessels engaged in transport to or from U.S. ports. Therefore, the costs for reporting the lost or jettisoned cargo must be accounted for throughout the entire applicable population of 6,436 vessels, as reported in Table 3.

For the years 2009 through 2013, there were only five incidents of containers lost or damaged at sea and reported to the Coast Guard. As previously noted, industry experts assert that many incidents of lost or jettisoned cargo are not reported to the appropriate authorities. To test this assertion, we developed an estimate of lost or jettisoned cargo incidents that are subject to Coast Guard rules.

As the base of our estimate, we used the annual estimate of 1,679 containers lost at sea worldwide, as reported by the World Shipping Council (WSC) in its 2014 report [13] to the IMO's Sub-Committee on Carriage of Cargoes and Containers.[14] The WSC's estimate is based on a survey of their membership. The survey respondents accounted for 70 percent of the world's container-ship capacity. The WSC adjusted the survey data to account for the 30 percent non-respondents. They also prepared two estimates, one without catastrophic events and the other that included the less-frequent catastrophic ones with large numbers of lost containers. We reviewed the WSC's methodology and we are satisfied that it produced a valid estimate. As we are using a 10-year forecast for our analysis, we needed to account for the low frequency-high consequence events, and used the higher annual estimate that included the catastrophic events.

However, the WSC report was not categorized by route or flag of the vessel. We derived the U.S. share of global container traffic using data reported by the U.S. Department of Transportation's Maritime Administration (MARAD), which reported in 2011 that there were 376,389 container ship visits worldwide,[15] and that, out of this total, 22,089 were at U.S. ports.[16] Thus, the U.S. share of global container traffic is 5.9 percent (22,089/376,389).

We used that 5.9 percent share to estimate that about 99 containers in U.S. traffic are lost annually (1,679 containers lost world-wide × 5.9 percent U.S. share of traffic, rounded). The 5 incidents resulted in a loss of a total of 25 containers, so we estimate on average there were 5 lost containers per incident. Using those data, we estimate that there will be 20 reports of lost containers to the Coast Guard (99 containers lost/5 containers per incident, rounded to the nearest 10) in the first year the rule becomes effective.

The Tioga Group, a freight transportation services consulting firm,[17] in its report [18] on the container market to the port authorities of Los Angeles and Long Beach, presents estimates of 4.9 percent annual compounded growth rate for the United States in container traffic from 2010 to 2020. We assume that the number of lost container incidents will grow proportionally with the growth in container trade. We applied the Tioga Group's estimate of 4.9 percent growth rate to the base estimate of 20 lost containers in Years 2 through 10 in this cost analysis. This yields an estimate of 31 incidents by Year 10 (the complete series is shown in the "Estimated Incidents" column of Table 6).

iii. Costs. When cargo is lost or jettisoned, the vessel staff already collects data for company purposes.[19] Thus, the only additional cost for compliance with this rule is the time to report the data to the Coast Guard and for the Coast Guard to record the data. Coast Guard staff who are familiar with vessel operations and incident reporting estimated that it will take 0.25 hours for a Master or other senior ship's officer to compile a report and transmit it to the Coast Guard.

The wage rate for the Master was obtained from the U.S. Bureau of Labor Statistics (BLS), using Occupational Series 53–5021, Captains, Mates, and Pilots of Water Vessels. The BLS reports that the hourly rate for a Master is $36.34 per hour.[20] To account for benefits, the load factor, or ratio between total compensation and wages is calculated at 1.44,[21] using BLS data. The fully loaded wage rate for a Master is estimated at $53 per hour ($36.34 base wages × 1.44 load factor, rounded up to capture the entire cost). The cost for the additional time to report an incident is $13.25 ($53 × 0.25).

Similarly, we estimate that it will take a quarter of an hour for Coast Guard personnel at the E–4 level to record the data. The fully loaded wage rate for an E–4 rating is $42, per Commandant Instruction 7310.1N. [22] The unit cost for the Coast Guard is $10.50 ($42 per hour × 0.25 hours).

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[13] The report is on WSC's Web site: *http://www.worldshipping.org/industry-issues/safety/Containers_Lost_at_Sea_-_2014_Update_Final_for_Dist.pdf.*

[14] Report number CCC 1/NF 9, dated June 27, 2014.

[15] See *http://www.marad.dot.gov/documents/Vessel_Calls_at_US_Ports_Snapshot.pdf*, p. 7, "Global Vessel Calls by Country, 2011."

[16] See *http://www.marad.dot.gov/documents/Vessel_Calls_at_US_Ports_Snapshot.pdf*, p. 3. "Containership Calls at U.S. Ports by Size, 2006–2011."

[17] For information on The Tioga Group, see *www.tiogagroup.com.*

[18] The Tioga Group, Inc. and IHS Global Insight, "San Pedro Bay Container Forecast Update", Exhibit 33: Total U.S. Loaded Total TEU and CAGRs, p. 33, *www.portoflosangeles.org/pdf/spb_container_forecast_update_073109.pdf.*

[19] Captain James J. McNamara, "Containers and Cargo Lost Overboard", p. 2. National Cargo Bureau; conference of the International Union of Marine Insurers; September 13, 2000, *http://www.iumi.com/images/stories/IUMI/Pictures/Conferences/London2000/Wednesday/02%20mcnamara%20cargo.pdf.*

[20] Mean wage, *http://www.bls.gov/oes/2013/may/oes535021.htm.*

[21] Load Factor calculation, source: *http://www.bls.gov/news.releases/archives/ecec_09112013.htm*, all Workers Total compensation, $31,00/Wages and salaries, $21.44.

[22] *http://www.uscg.mil/directives/ci/7000-7999/CI_7310_1N.pdf.*

As shown in Table 5, the unit cost for reporting lost or jettisoned cargo is $23.75.

TABLE 5—UNIT COST FOR REPORTING LOST OR JETTISONED CARGO

Task	Time (hours)	Wage rate	Cost
Master to report	0.25	$53	$13.25
CG data entry (E4)	0.25	42	10.50
Total			23.75

Sources: BLS, Coast Guard estimates.

The baseline estimate of lost or jettisoned cargo incidents, the growth rate, and the unit cost data provide the inputs into the 10-year cost schedule. Table 6 displays the input data and the resulting cost estimates on an undiscounted basis and discounted at 7-percent and 3-percent interest rates.

TABLE 6—COST SCHEDULE FOR REPORTING LOST OR JETTISONED CARGO

Year	Estimated incidents	Rounded incidents	Industry cost	Coast Guard cost	Total cost	Discounted	
						7%	3%
1	20	20	$265	$210	$475	$444	$461
2	20.98	21	278	221	499	436	470
3	22.01	22	292	231	523	427	479
4	23.09	23	305	242	547	417	486
5	24.22	24	318	252	570	406	492
6	25.41	25	331	263	594	396	497
7	26.66	27	358	284	642	400	522
8	27.97	28	371	294	665	387	525
9	29.34	29	384	305	689	375	528
10	30.78	31	411	326	737	375	548
Total			3,313	2,628	5,941	4,063	5,008
Annualized						578	587

To provide an estimate of costs by flag status, we extracted from the Coast Guard's SANS database the vessels calling on U.S. ports in 2011.[23] We divided the vessels into U.S.- and foreign-flagged status. Table 7 presents the data and shows that in 2013, U.S.-flagged vessels accounted for 11.8 percent of the visits by vessels that would be subject to this interim rule.

TABLE 7—2013 VISITS TO U.S. PORTS BY FLAG-STATUS OF VESSELS NON-BULK TRADE

Flag	Visits	Percent
United States	2,955	11.8
Foreign	22,001	88.2
Total	24,956	100.0

We produced an estimate for U.S. costs of lost or jettisoned cargo by applying the 11.8 percent of visits by U.S.-flagged vessels from Table 7 to the cost estimates from Table 6. Note that U.S. costs include both costs to U.S.-flagged vessels and the Coast Guard. Table 8 displays the data for the U.S. costs.

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[23] 2011 is the most recent year of verified data.

TABLE 8—COST SCHEDULE FOR U.S.-FLAGGED VESSELS FOR REPORTING LOST OR JETTISONED CARGO

Year	Rounded incidents	Industry cost	CG cost	Total cost	Discounted	
					7%	3%
1	2	$27	$21	$48	$45	$47
2	2	27	21	48	42	45
3	3	40	32	72	59	66
4	3	40	32	72	55	64
5	3	40	32	72	51	62
6	3	40	32	72	48	60
7	3	40	32	72	45	59
8	3	40	32	72	42	57
9	3	40	32	72	39	55
10	4	53	42	95	48	71
Total		387	308	695	474	586
Annualized					67	69

We obtained the costs of reporting lost or jettisoned cargo for non-U.S.-flagged vessels by subtracting the U.S. costs, as reported in Table 8, from the costs as displayed in Table 6. Table 9 presents the results of these calculations.

TABLE 9—COST SCHEDULE FOR NON-U.S.-FLAGGED VESSELS FOR REPORTING LOST OR JETTISONED CARGO

Year	Rounded incidents	Industry cost	Coast Guard cost	Total cost	Discounted	
					7%	3%
1	18	239	189	428	400	416
2	19	252	200	452	395	426
3	19	252	200	452	369	414
4	20	265	210	475	362	422
5	21	278	221	499	356	430
6	22	292	231	523	348	438
7	24	318	252	570	355	463
8	25	331	263	594	346	469
9	26	345	273	618	336	474
10	27	358	284	642	326	478
Total		2,930	2,323	5,253	3,593	4,430
Annualized					512	519

iv. Benefits. A 2011 news release from the Monterey Bay Aquarium Research Institute (MBARI)[24] stated that containers that fall from ships can "float at the surface for months" and that "most eventually sink to the seafloor." While they float they can present a hazard to navigation. However, sunken containers may pose immediate and long-term threats to the marine environment. The MBARI news release also stated that "[N]o one knows what happens to these containers once they reach the deep seafloor" and that "[p]erhaps 10 percent of shipping containers carry household and industrial chemicals that could be toxic to marine life." The small number of MISLE incidents provides additional information. Of the 25 containers, one container held 22,500 pounds of used batteries and another held an unspecified hazardous material.

The immediate benefit of the reporting provisions is that they will enhance the Coast Guard's ability to identify potential problems with securing equipment, locate and warn mariners about drifting containers that endanger safe navigation, and assess and respond to any potential environmental hazard created by the cargo loss. In the longer term, having complete and accurate data on lost cargo incidents will enable the Coast Guard and other parties to identify industry trends and track potential long-term threats to the marine environment from sunken containers.

v. Alternatives. We considered possible alternatives to this rule. One possibility, as suggested in the SNPRM, would be to limit the reporting of lost containers to only those containing hazardous materials. However, we consider any overboard container to be a potential hazard to navigation and, as noted above, the contents may pose a long-term threat to the marine environment. To ensure safety of navigation and the marine environment, we believe all lost or jettisoned cargo should be reported. As one commenter noted, the containers may not disintegrate for hundreds of years once they reach the floor. Thus, the long-term impacts on the environment are extremely hard to assess.

Another alternative we considered was to reduce the amount of information to be sent to the Coast Guard in order to minimize recordkeeping burden. We examined the data specified in this rule and determined that all of it would be needed by the Coast Guard in order to completely evaluate the situation and determine the appropriate response. Therefore, we believe that the reporting requirements in this rule will provide the Coast Guard with sufficient information to fulfill its missions of maritime safety and marine environmental protection while minimizing the vessel's recordkeeping and reporting burdens.

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[24] *http://www.mbari.org/news/news_releases/2011/containers/containers-release.html.*

b. CSM Requirements.

i. Current practices, applicable population, and description of changes and edits. As stated in Section IV of this preamble, Background and Regulatory History, the Coast Guard has developed guidance,[25] based on IMO Circular 1353, for implementing SOLAS provisions for cargo securing manuals.

Under the Coast Guard's safety and security vessel examinations program, the Coast Guard checks that the subject vessels in U.S. ports have CSMs and that the crews follow them. MISLE data show that from 2011 through 2013, the 83 U.S.-flagged vessels that are part of the affected population were subject to 646 inspections. In all of these inspections there were no citations for a deficient CSM.

MISLE also recorded that from 2011 through 2013, the Coast Guard conducted 14,358 vessel inspections of foreign-flagged vessels and found problems relating to CSMs in only 9 instances. These data indicate an ongoing compliance process for both U.S.- and foreign-flagged vessels subject to CSM rules. Therefore, the Coast Guard anticipates that the only costs regarding the CSM requirement, once the requirements of SOLAS and Coast Guard guidance are moved into the CFR, would be those associated with owners or operators of the few deficient vessels who are prompted to ensure their CSMs are fully compliant with SOLAS prior to entering U.S. waters.

Tables 10 and 11 present the change matrix for the edits to Titles 33 and 46 of the CFR, respectively, that relate to the CSM requirements of the interim rule. Each matrix summarizes the specific edit or change, the affected population, and the economic impact.

TABLE 10—CHANGE MATRIX FOR ADDING CSM REQUIREMENTS TO 33 CFR

Reference & description	Affected population	Economic impact
97.100 *Applicability:*		
. . . (a)(1), U.S. vessels	U.S. cargo vessels, non-U.S. cargo vessels of *500 gross tons or more* in U.S. waters.	None, administrative only.
. . . (a)(2), voluntary compliance	U.S. vessels requesting coverage	No change, codifies guidance currently located in NVIC.
. . . (b), exemption for Ready Reserve and public vessels.	Ready Reserve and public vessels	None, these vessels currently are exempted.
. . . 97.105 Definitions	All vessels and approval organizations	None, administrative only.
. . . 97.110 Incorporation by reference (lists IBR references).	All affected vessels and approval organizations.	None, administrative only.
97.120 *Cargo Securing Manuals:*		
. . . (a)(1), CSMs required	SOLAS vessels and non-U.S., non-SOLAS vessels noted with deficient CSMs by Coast Guard.	Cost of developing CSM for noncompliant vessels.
. . . (a)(2), CSAP required after 2015	Non-SOLAS vessels	Edit to close regulatory gap. No costs, no current vessels affected and none expected in future.
. . . (b), authorizes CG enforcement	All U.S.- and foreign-flagged vessels subject to the rule.	No cost, provides authority for current CG compliance activities.

Source: Coast Guard analysis.

TABLE 11—CHANGE MATRIX FOR EDITS TO 46 CFR 97 THAT APPLY TO U.S. SOLAS VESSELS

Reference & description	Affected population	Economic impact
97.12–10 Cargo securing manuals, new section to reference new 33 CFR 97.120.	Owners and operators of U.S. SOLAS vessels	Administrative edit, all costs accounted for in 33 CFR 97.120.

Source: Coast Guard analysis.

ii. Affected population. As stated earlier, the Coast Guard's current safety and security examinations include checking to see if a subject vessel has a current CSM and that the crew follows it. The inspection results indicate that the 83 U.S.-flagged vessels in international trade are all in the 500 gross tons or more class and that they comply with the SOLAS CSM rules. Under an assumption that they will continue with those practices, this establishes a baseline of current compliance throughout the 10-year analysis period. In this scenario, the U.S.-flagged vessels will incur no additional costs from this rule. However, to conduct a thorough regulatory analysis, we included the 83 U.S.-flagged vessels in the analysis and assumed that they will obtain a SOLAS-compliant CSM in the first year the rule is in effect. A review of the year-built data for these vessels shows that the most recently built was in 2009. We assume that this trend of no new builds will continue and that the population will remain stable at 83 vessels per year throughout the 10-year analysis period.

Additionally, the interim rule requires that a CSM must be revised if one of these two criteria are met:

1. The vessel changes its type. As an example, a former break-bulk carrier is modified to become a container ship.
2. An existing vessel changes 15 percent of its cargo securing systems or more than 15 percent of its portable securing devices.

MISLE data indicates that none of the subject U.S.-flagged vessels have changed vessel type from 2001 through 2012. We assume that this trend will continue and that no vessels will change type during our analysis period. From information provided by an approved organization,[26] we estimated that, on an annual basis, 11.3 percent of the U.S.-flagged fleet revises it CSM based on the second criterion described above. We applied this rate to the subject 83 U.S-flagged vessels to estimate that 9 vessels per year will revise their CSMs (83 × 11.3 percent, rounded) in Years 2 through 10 of the analysis period.

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[25] NVIC 10–97.

Foreign-flagged vessels that are 500 gross tons or more follow SOLAS rules and current Coast Guard guidance. We estimated the costs of compliance for these vessels based on the following assumptions:

(1) In the absence of the rule, the current deficiency rate for subject foreign-flagged vessels would continue.

(2) Under the rule, the increased enforceability posture from codifying the CSM rules will lead all vessels to comply with the SOLAS standards and current Coast Guard guidance prior to entering U.S. waters. That is, the deficiency rate will be reduced to zero for foreign-flagged vessels.

We reported above that there were nine deficiencies related to CSMs from 2011through 2013. These deficiencies are comprised of five that were missing approval from an authorized organization, three that did not have a CSM on the vessel, and one that had a CSM with missing sections. Table 12 presents the data from 2011 through 2013 for the calculation of a deficiency rates by year and an annual average for the 3 years.

TABLE 12—ANNUAL CSM DEFICIENCY RATE

Year	Vessel examinations	CSM deficiencies	Deficiency rate (percent)
2011	5,135	2	0.04
2012	4,464	4	0.09
2013	4,759	3	0.06
Total	14,358	9	*0.06

* Average deficiency rate.

We used the average deficiency rate of 0.06 percent throughout our 10-year analysis period. The estimate of the number of deficient CSMs in any year equals the estimate of the vessel population for that year multiplied by the deficiency rate.

As reported in Table 3 in the "SOLAS Class" subtotal, there are 6,353 foreign-flagged vessels that are currently subject to the CSM requirements. Applying the 0.06 percent deficiency rate from Table 12 yields an estimate of four vessels that will need to remedy deficient CSMs in the first year the rule comes into effect.

In the analysis of the reporting requirements, we cited the Tioga Group's report on the container market that growth in container shipments to the United States is expected to increase,[27] so a flat extrapolation of the seven CSMs in the first year through Years 2 through 10 of the analysis period would result in an underestimate.

We used the Tioga Group's estimate of a 4.9 percent rate for our estimate for growth in our 10-year analysis period. Currently, we do not have detailed information on the current and projected capacity utilization of container ships visiting U.S. ports, so we posited that the trips per year of the affected vessels would remain constant through the analysis period. With that assumption, we applied the 4.9 percent annual growth rate to the fleet of foreign-flagged vessels serving U.S. ports.

For Years 2 through 10, the base population is the base population from the previous year multiplied by the 4.9 percent growth rate. The resulting estimates of the base populations are shown in the "Base Population" column of Table 14.

iii. Costs. To obtain a current estimate for the cost of developing a CSM, we contacted industry cargo securing subject matter experts in 2013.[28] These experts are familiar with the entire development of CSMs, including vessel survey, evaluation of cargo securing equipment and procedures, preparation of manuals, and training of crews. From the information they provided, we estimate that the cost to develop a CSM will range between $7,500 and $10,000, depending on factors such as the size and type of vessel. We used the midpoint of this range, $8,750 (($7,500 + $10,000)/2), as the unit cost of developing a CSM.

We anticipate that a CSM will be revised to either remedy a deficiency or because the vessel met the previously discussed criterion of new cargo securing systems. We do not have detailed descriptions of each deficiency or changes in cargo securing equipment, so for the unit cost, we assume that a vessel will revise the CSM using an existing survey of the vessel. A 2013 study conducted by ABS Consulting, Inc. for the Coast Guard provided estimates on the costs of a suite of marine engineering and naval architecture services.[29] That study estimated that the average cost of a survey for a freight ship is $1,125. We estimate the unit cost to remedy a deficiency as the average cost of developing a CSM [$8,750 = ($7,500 + $10,000)/2)] less the average cost of a survey. This yields an estimated unit cost of $7,625 ($8,750 − $1,125).

The costs to the Federal government are accounted for by the oversight actions performed by the authorized approval organizations. These actions include reviewing new or revised CSMs, issuing letters of approval, and, for CSMs that are not approved, issuing letters that explain why the CSMs were not approved. We anticipate that the reviews of the CSM will be conducted by a marine engineer or naval architect. We estimate that each review will take on average 2 working days and another hour will be needed to prepare the appropriate correspondence to the vessel's managers. Thus, the attributed burden to the Federal government for each review is 17 hours ((2 × 8) + 1 = 17).

We estimate that the average loaded (including benefits) hourly wage for a marine architect or naval engineer is

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[26] To protect proprietary information, we cannot provide the name of the organization.

[27] The Tioga Group, Inc. and IHS Global Insight, "San Pedro Bay Container Forecast Update", Exhibit 33: Total U.S. Loaded Total TEU and CAGRs, p. 33, *www.portoflosangeles.org/pdf/spb_container_forecast_update_073109.pdf.*

[28] The data obtained contain proprietary information and are not available publicly.

[29] ABS Consulting, Inc, "Study of Marine Engineering and Naval Architecture Costs for Use in Regulatory Analyses," Table 5, p. 26. A copy of this study can be found in the docket for this rulemaking.

$64 per hour.[30] The unit cost to review one CSM is $1,088 (17 hours × $64 per hour). Table 13 shows the undiscounted costs to industry and the Federal government for the 10-year analysis period.

Costs for Foreign-Flagged Vessels

As foreign-flagged vessels are obtaining and revising CSMs under the auspices of their flag states, their only cost for this interim rule is to remedy deficiencies. The cost in each year is the number of deficient vessels times the unit cost of $7,625. Table 13 presents the undiscounted cost estimate for foreign-flagged vessels over the 10-year period.

TABLE 13—COSTS TO FOREIGN-FLAGGED VESSELS FOR DEVELOPING CSMS

Year	Base population	Remedied	Unit cost	Total cost
1	6,353	4	$7,625	$30,500
2	6,664	4	7,625	30,500
3	6,991	4	7,625	30,500
4	7,334	4	7,625	30,500
5	7,693	5	7,625	38,125
6	8,070	5	7,625	38,125
7	8,465	5	7,625	38,125
8	8,880	5	7,625	38,125
9	9,315	6	7,625	45,750
10	9,771	6	7,625	45,750
Total		48		366,000

Costs for U.S.-Flagged Vessels

As discussed previously, all 83 U.S.-flagged vessels have CSMs and have operated under them for over a decade. In addition, current business practices, particularly the requirements of insurers, would also indicate the use of a CSM. For these reasons, and as presented in the Regulatory Analysis of the NPRM, the requirements in this interim rule are not expected to result in a change in practice or incur a cost for the 83 U.S.-flagged vessels.

For the purposes of this regulatory analysis, we also compute costs assuming a baseline without CSMs for the 83 U.S.-flagged vessels. The cost for U.S.-flagged vessels to develop CSMs is presented in Table 14.

TABLE 14—COSTS OF DEVELOPING CSMS FOR U.S. VESSELS TO INDUSTRY AND THE FEDERAL GOVERNMENT

Year	Base population	Industry CSM cost	Industry cost	Federal Government cost	Total cost
1	83	$8,750	$726,250	$90,304	$816,554
2	9	7,625	68,625	9,792	78,417
3	9	7,625	68,625	9,792	78,417
4	9	7,625	68,625	9,792	78,417
5	9	7,625	68,625	9,792	78,417
6	9	7,625	68,625	9,792	78,417
7	9	7,625	68,625	9,792	78,417
8	9	7,625	68,625	9,792	78,417
9	9	7,625	68,625	9,792	78,417
10	9	7,625	68,625	9,792	78,417
Total	164		1,343,875	178,432	1,522,307

Table 15 presents the total costs for foreign-flagged vessels and U.S.-flagged vessels assuming a pre-CSM baseline on an undiscounted basis and the total costs discounted at rates of 7 percent and 3 percent. As shown in Table 15, the total 10-year cost for upgrading CSMs at a 7-percent discount rate is $1,490,587, or $212,226 on an annualized basis.

TABLE 15—CSMS—UNDISCOUNTED COMPONENT AND TOTAL COSTS; AND TOTAL COSTS AT DISCOUNT RATES OF 7 PERCENT AND 3 PERCENT

Year	Undiscounted			Discounted	
	U.S.-flagged cost	Foreign-flagged cost	Total cost	7%	3%
1	$816,554	$30,500	$847,054	$791,639	$822,383
2	78,417	30,500	108,917	95,132	102,665

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[30] Mean hourly wage of $44.10 for a marine engineer/naval architect from the Bureau of Labor Statistics (*http://www.bls.gov/oes/2011/may/oes172121.htm*) multiplied by load factor of 1.44 to account for benefits (*ftp://ftp.bls.gov/pub/special.requests/ocwc/ect/ececqrtn.pdf*).

TABLE 15—CSMS—UNDISCOUNTED COMPONENT AND TOTAL COSTS; AND TOTAL COSTS AT DISCOUNT RATES OF 7 PERCENT AND 3 PERCENT—Continued

Year	Undiscounted			Discounted	
	U.S-flagged cost	Foreign-flagged cost	Total cost	7%	3%
3	78,417	30,500	108,917	88,909	99,674
4	78,417	30,500	108,917	83,092	96,771
5	78,417	38,125	116,542	83,093	100,530
6	78,417	38,125	116,542	77,657	97,602
7	78,417	38,125	116,542	72,577	94,759
8	78,417	38,125	116,542	67,829	91,999
9	78,417	45,750	124,167	67,539	95,164
10	78,417	45,750	124,167	63,120	92,392
Total	1,522,307	366,000	1,888,307	1,490,587	1,693,939
Annualized				212,226	198,581

iv. Benefits. The benefit of adding the SOLAS requirements and current Coast Guard guidance on CSMs to the CFR is increased Coast Guard enforcement authority. We previously cited the statistics from the Coast Guard's CSM inspection activities from 2009 through 2011 for both U.S.- and foreign-flagged vessels. However, as noted in Section IV, Background and Regulatory History, of this preamble, the only current U.S. implementation of the CSM is via current Coast Guard guidance, which is unenforceable. Incorporating these rules into the CFR elevates the guidelines and standards to being a Federal regulation. As described in Section III, Basis and Purpose, of this preamble, the Coast Guard has existing authorities to inspect vessels, regulate an inspected vessel's operation, fittings, equipment, and appliances, and implement SOLAS. The Coast Guard believes that it can enforce the provisions of this rule under these authorities.

v. Alternatives. Alternatives to this provision of the rule that we considered include various ways to apply the requirements to prepare and implement CSMs to U.S.-flagged vessels in coastwise trade. The NPRM published in 2000 presented five options for applying CSM regulations to U.S. domestic voyages. Table 16 presents descriptions of these options and a summary of the comments.

TABLE 16—OPTIONS TO EXTEND CSM REQUIREMENTS TO U.S. DOMESTIC VOYAGES

Option No.	Description	Summary of comments
1	Extend SOLAS requirements to domestic voyages	4 supported, 5 opposed for these reasons: • Preferred compromise of Options 1 & 2; • Not requiring regular reviews; • Too restrictive; • Require too much standardization; and • Would not work for seagoing barges as no two barge cargoes are identical.
2	Vessel specific standards, Coast Guard approval	1 supported, 5 opposed for these reasons: • Evaluate against experience with continuous examination program and noted similarity with Option 5; • Too many variables causing unneeded burden; • Would not work, but did not give specific reasons; • Second choice; and • Preferred compromise of Options 1 and 2.
3	Certificate for carrying hazardous materials	One commenter stated its decision would depend on specific requirements, and 3 commenters opposed for these reasons: • Surveyors for multiple voyages not feasible for cost and availability; • Could not ensure surveyor availability; and • High costs of surveyors.
4	Allow each vessel to choose from among Options 1, 2, and 3	One commenter noted that companies supporting domestic rules would find this attractive, but did not state its own opinion. Another stated that it combined the strengths and weaknesses of the other Options. One opposed for unstated reasons and another was opposed because the "menu of options" would cause confusion.
5	Standards developed with industry	Three comments supported, 1 for unstated reasons and 2 because of its flexibility; and 1 commenter was opposed because it would not ensure meeting needs of different vessel types and operations.

The options presented in the NPRM were only outlined and did not have cost estimates. We developed a cost estimate for Option 1 that would extend SOLAS requirements to domestic vessels. We added these details to Option 1 to make the calculations:

- The affected population will be U.S.-flagged vessels in coastwise trade. The geographic identification was vessels with coastwise route certifications. We identified 688 vessels from MISLE that met these requirements, comprised of 195 freight barges, 160 freight ships, and 333 offshore supply vessels.
- In general, the vessels in the U.S. affected population for this alternative are smaller than the foreign-flagged vessels that comprise the affected population of the regulation. Data comparisons for the U.S. fleet shows average gross tons of 8,165 and average length of 326 feet. The comparable data for the foreign-flagged vessels is average gross tonnage of 31,306 and average length of 619 feet. Therefore, for the unit cost of the U.S. coastwise vessels, we assigned the low-end value of $7,500, which came from the range supplied by the subject matter experts we contacted. The recent history of new builds is projected to continue through the 10-year analysis period. MISLE reported 22 new vessels per year from 2009 through 2012, and we used this in our analysis.
- A phase-in period was not in the NPRM, but we added a 3-year phase-in period to this interim rule to mitigate the burden on both vessel owners and the authorized approval organizations. We assume that vessel owners will distribute the certification of the manuals for their vessels evenly over the phase-in period. This will enable vessel owners and authorized approval organizations to schedule cargo securing approvals in conjunction with vessel down-time, such as scheduled examinations or times of vessel repairs and upgrades.

With these parameters, we developed a 10-year cost schedule for Option 1. Because the costs to foreign-flagged vessels would be the same for Option 1 as for the preferred alternative, the data presented show the marginal costs for Option 1. The annualized cost, using a 7-percent discount rate, would be $807,605. The cost estimates are displayed in Table 17.

TABLE 17—COST ESTIMATE FOR OPTION 1, EXTEND CSM REQUIREMENTS TO DOMESTIC VESSELS

Year	Existing vessels	New vessels	Total vessels	Unit cost	Total cost	Discounted	
						7%	3%
1	229	22	251	$7,500	$1,882,500	$1,759,346	$1,827,670
2	229	22	251	7,500	1,882,500	1,644,248	1,774,437
3	230	22	252	7,500	1,890,000	1,542,803	1,729,618
4	0	22	22	7,500	165,000	125,878	146,600
5	0	22	22	7,500	165,000	117,643	142,330
6	0	22	22	7,500	165,000	109,946	138,185
7	0	22	22	7,500	165,000	102,754	134,160
8	0	22	22	7,500	165,000	96,032	130,253
9	0	22	22	7,500	165,000	89,749	126,459
10	0	22	22	7,500	165,000	83,878	122,775
Total	688	220	908		6,810,000	5,672,277	6,272,487
Annualized						807,605	735,327

The goal of Option 1 is to reduce the occurrence and impacts of lost containers in U.S. coastwise trade. However, the comments to the NPRM indicate that this is not a significant problem. One commenter stated that cargo losses from barges are rare, another stated that seagoing barges "are generally safe from cargo loss," and another commenter stated that "most cargo losses result from container structural problems that the vessel owner or operator cannot know about or prevent." However, as described above, the reporting of these incidents is uncertain. We anticipate that, with the more accurate reporting required by this interim rule, we will be able to validate this assertion. Additionally, our initial cost estimates, as presented in Table 17, indicate that industry would incur annualized costs, discounted at 7 percent, of $807,605 beyond what is in this rule. Therefore, this interim rule focuses exclusively on vessels in international trade. However, the Coast Guard can reevaluate this position and initiate another rulemaking for the U.S. coastwise trade if new information indicates either underreporting or an upward trend of lost containers.

c. Approval of Authorized Organizations

The Coast Guard authorizes classification societies and other organizations to review and approve CSMs on its behalf. The procedures for these organizations are currently found in Coast Guard guidance and cover selection criteria, information required by organizations applying for authorization status, and the Coast Guard's application review procedures, termination of authorization procedures, and appeals procedures.

Following the procedures in current Coast Guard guidance, the Coast Guard has authorized these six classification societies to review and approve CSMs: American Bureau of Shipping (ABS), Det Norske Veritas (DNV), Lloyd's Register of Shipping (LR), Germanischer Lloyd (GL), RINA S.p.A, and ClassNK (NK).[31] We anticipate that no other classification societies will be applying for CSM approval authority in the near future.[32]

However, current Coast Guard guidance is not legally enforceable. This interim rule will incorporate these procedures from guidance into the CFR with only some minor editorial changes, such as updating the address of Coast Guard Headquarters. Therefore, we believe there will be no additional regulatory costs associated with the codification of these application procedures. Table 18 presents the change matrix for the codification of the class society approval guidance into the CFR and summarizes the specific edit or change, the affected population, and the economic impact.

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[31] List of classification societies authorizations: *http://www.uscg.mil/hq/cg5/acp/docs/ClassSocietyAuths22Dec2013.pdf.*

[32] For more information see the final rule "Approval of Classification Societies", VII. A, "Regulatory Planning and Review", 77 FR 47548, RIN 1625–AB35).

TABLE 18—CHANGE MATRIX FOR INCORPORATING CLASS SOCIETY APPROVAL PROCEDURES INTO 46 CFR

Reference & description	Affected population	Economic impact
97.100 Applicability:		
. . . (a)(4), organizations applying for CSM approval authority.	New applicants	No impact, incorporates current guidance into regulations.
97.115 Situation requiring report, criteria for reporting lost cargo.	Vessels subject to the rule that lose cargo overboard.	Costs for correction of noncompliance with existing requirements.
97.200 CSM approval for U.S. vessels on international voyages:		
. . . (a)(1), authorized applicants include owner, operator, or agent.	Owners, operators, and agents, of new U.S. vessels in international trade.	Administrative change, guidance only referenced owner.
. . . (a)(2), CG oversight of approval authority applications.	Organizations applying for CSM approval authority.	No change, incorporates current guidance into regulations.
. . . (a)(3), application procedures	U.S. vessels in international trade	No change, incorporates current guidance into regulations.
. . . (a)(4), approval authority retains a copy.	Authorized approval organizations	No change, incorporates current guidance into regulations.
. . . (b), approval letter contents	Authorized approval organizations	No change, incorporates current guidance into regulations
. . . (c), disapproval procedures	Authorized approval organizations	No change, incorporates current guidance into regulations.
. . . (d), resubmit procedures	Owners or operators resubmitting a CSM	No change, incorporates current guidance into regulations.
. . . (e), documents kept on vessel	Owners or operators of U.S. vessels subject to the rule.	No change, incorporates current guidance into regulations.
97.205 Requirements for amending an approved CSM, amending procedures.	Owners or operators of U.S. vessels subject to the rule.	No change, incorporates current guidance into regulations.
97.210 Appeals, appeals procedures	Owners or operators of U.S. vessels subject to the rule and authorized approval organizations.	No change, incorporates current guidance into regulations
97.300 Authorized CSM approval authorities, lists approved organizations.	ABS, DNV, LR, GL, RINA, NK, National Cargo Bureau.	No change, incorporates current guidance into regulations.
97.305 Requests for authorization, application process.	Organizations seeking to become approved organizations.	No change, incorporates current guidance into regulations.
97.310 Criteria for authorization, evaluation criteria.	CG and organizations seeking to become approved organizations.	No change, incorporates current guidance into regulations.
97.315 Requirements for authorized approval organizations, responsibilities of CG and authorized approval organizations.	CG and authorized approval organizations	No change, substantively incorporates and rewords current guidance into regulations.
97.320 Revocation of authorization, procedures for CG revoking an authorization.	CG and referenced organizations	No change, substantively incorporates and rewords current guidance into regulations.

Source: Coast Guard analysis.

We considered alternatives to these changes and edits, and we concluded that there were no viable alternatives. The procedures in current Coast Guard guidance provide a complete description of all processes needed for approval and oversight of the subject organizations. Reducing or eliminating any of them, such as the one covering appeals, would leave a gap in the approval or oversight processes. We did not identify any weaknesses or gaps in the current Coast Guard guidance, other than the editorial changes. We also concluded that the recordkeeping information in the current Coast Guard guidance provides complete documentation for all the involved parties—vessel owners or operators, and approved organizations. Reducing or eliminating any of the recordkeeping rules would run the risk of producing a gap in the documentation. Conversely, adding additional recordkeeping rules would only increase associated burdens, but not provide any additional useful information.

In summary, the rules governing organizations approved to issue CSMs will codify current procedures with no associated costs to industry or the government. The benefit of these rules is that they will provide a regulatory basis for the Coast Guard's oversight of organizations authorized to approve CSMs.

d. Review of Costs and Benefits. The total cost of this interim rule is for the two cost elements: (1) Reporting of lost or Jettisoned Cargo; and (2) CSM Requirements. Table 19 presents the 10-year total cost schedule assuming a pre-CSM baseline for undiscounted costs, and the discounted costs at 7-percent and 3-percent interest rates.

TABLE 19—SUMMARY OF THE 10-YEAR TOTAL COST OF INTERIM RULE, UNDISCOUNTED AND DISCOUNTED AT INTEREST RATES OF 7 PERCENT AND 3 PERCENT

Year	Undiscounted			Discounted	
	Lost or jettisoned cargo	CSM plans	Total	7%	3%
1	$475	$847,054	$847,529	$792,083	$822,844
2	499	108,917	109,416	95,568	103,135
3	523	108,917	109,440	89,336	100,153
4	547	108,917	109,464	83,510	97,257
5	570	116,542	117,112	83,499	101,022
6	594	116,542	117,136	78,053	98,100
7	642	116,542	117,184	72,976	95,281
8	665	116,542	117,207	68,216	92,524
9	689	124,167	124,856	67,913	95,692
10	737	124,167	124,904	63,495	92,940
Total	5,941	1,888,307	1,894,248	1,494,649	1,698,948
Annualized				212,804	199,169

Table 20 summarizes the undiscounted costs disaggregated by flag, requirement, and sector.

TABLE 20—10-YEAR UNDISCOUNTED COSTS BY FLAG, REQUIREMENT, AND SECTOR

Flag	Requirement	Industry	Federal Government	Total
United States	Lost Cargo	$387	$308	$695
	CSM	1,343,875	178,432	1,522,307
	U.S. Total	1,344,262	178,740	1,523,002
* Foreign	Lost Cargo	2,930	2,323	* 5,253
	CSM	366,000	0	366,000
	Foreign Total	368,930	2,323	371,253
Total		1,713,192	181,063	1,894,255

Note: Subtotals and Totals do not match with those in other tables due to independent rounding.

The primary benefit of this interim rule is that it places into the CFR rules and procedures for the cargo securing plans, the approval and oversight of organizations authorized to approve CSMs, and the reporting of lost or jettisoned cargo. Additionally, the reporting requirements for the lost or jettisoned cargo will provide the Coast Guard with additional information to track and monitor the effects on both navigation and the environment, and to take any appropriate enforcement actions. Overall, the interim rule will support the Coast Guard's missions of maritime safety and stewardship.

e. Preliminary analysis of expanding the affected population.

In Section V, Summary of the Rule, and Section VI, Discussion of Comments on SNPRM and Changes, we requested comments on our proposal to include self-propelled vessels less than 500 gross tons in the affected population. We conducted a preliminary analysis of the economic impacts of the proposal and summarize our findings below.

The proposal would add an additional 45 foreign-flagged vessels, resulting in a new total of 6,398 foreign-flagged vessels. Combined with the 83 U.S.-flagged vessels, the total affected population would be 6,481 vessels.

The only requirement that would be affected is the one requiring a subject vessel to have and follow an approved CSM. Of the 45 new vessels, 42 currently hold SOLAS cargo safety certificates. For this preliminary analysis we assumed that the three vessels without a cargo safety certificate would need to obtain an approved CSM. This would add an additional 26,250 (3 vessels × 8,750 per new CSM). A revised 10-year cost estimate for this requirement based on these assumptions is presented in Table 21.

TABLE 21—COST OF CSM PLANS UNDER THE PROPOSED RULE (ADDING VESSELS UNDER 500 GT TO INTERIM RULE ESTIMATES), UNDISCOUNTED AND DISCOUNTED AT 7 PERCENT AND 3 PERCENT

Year	U.S.-flagged cost	Foreign-flagged	Total cost	7%	3%
1	$816,554	$53,375	$869,929	$813,018	$844,591
2	78,417	30,500	108,917	95,132	102,665

TABLE 21—COST OF CSM PLANS UNDER THE PROPOSED RULE (ADDING VESSELS UNDER 500 GT TO INTERIM RULE ESTIMATES), UNDISCOUNTED AND DISCOUNTED AT 7 PERCENT AND 3 PERCENT—Continued

Year	U.S.-flagged cost	Foreign-flagged	Total cost	7%	3%
3	78,417	30,500	108,917	88,909	99,674
4	78,417	30,500	108,917	83,092	96,771
5	78,417	38,125	116,542	83,093	100,530
6	78,417	38,125	116,542	77,657	97,602
7	78,417	38,125	116,542	72,577	94,759
8	78,417	38,125	116,542	67,829	91,999
9	78,417	45,750	124,167	67,539	95,164
10	78,417	45,750	124,167	63,120	92,392
Total	1,522,307	388,875	1,911,182	1,511,966	1,716,147
Annualized				215,270	201,185

The 7-percent annualized cost for the proposed modification to the CSM requirement is 215,270, compared to 212,226 for the interim rule, as shown in Table 15. Table 22 presents a revised 10-year schedule. It adds the 26,250 cost of new CSMs for the 3 vessels under 500 gross tons to the other requirements for reporting lost or jettisoned cargo and approval of classification societies.

TABLE 22—SUMMARY OF THE 10-YEAR TOTAL COST OF THE PROPOSED RULE (ADDING VESSELS UNDER 500 GT TO INTERIM RULE ESTIMATES) BY SECTOR, UNDISCOUNTED AND DISCOUNTED AT 7 PERCENT AND 3 PERCENT

Year	Industry	Government	Total	7%	3%
1	$779,890	$90,514	$870,404	$813,462	$845,052
2	99,403	10,013	109,416	95,568	103,135
3	99,417	10,023	109,440	89,336	100,153
4	99,430	10,034	109,464	83,510	97,257
5	107,068	10,044	117,112	83,499	101,022
6	107,081	10,055	117,136	78,053	98,100
7	107,108	10,076	117,184	72,976	95,281
8	107,121	10,086	117,207	68,216	92,524
9	114,759	10,097	124,856	67,913	95,692
10	114,786	10,118	124,904	63,495	92,940
Total	1,736,063	181,060	1,917,123	1,516,028	1,721,156
Annualized				215,848	201,772

With the addition of self-propelled vessels that are less than 500 gross tons, the annualized cost at a 7-percent discount rate increases to 215,848, compared to 212,804 for the interim rule, as shown in Table 19.

B. Small Entities

1. Summary of Findings

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) (RFA) and Executive Order (E.O.) 13272 require a review of proposed and final rules to assess their impacts on small entities. An agency must prepare an initial regulatory flexibility analysis (IRFA) unless it determines and certifies that a rule, if promulgated, would not have a significant impact on a substantial number of small entities. During the SNPRM stage, we published an IRFA to aid the public in commenting on the potential small business impacts of the proposals in the SNPRM. All interested parties were invited to submit data and information regarding the potential economic impact that would result from adoption of the proposals in the SNPRM.

Under the RFA, we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

We determined that this interim rule affects a variety of large and small businesses, not-for-profit organizations, and governments (see the "Description of the Potential Number of Small Entities" section below). Based on the information from this analysis, we found—

- Using size standards from the Small Business Administration (SBA), the 83 U.S-flagged vessels are controlled by 21 entities, none of which are small. The 6,353 foreign-flagged vessels are controlled by 1,023 entities. A review of the entities that control these vessels found that one foreign-flagged vessel is controlled by a non-U.S. not-for-profit entity that is not considered to be small, 7 foreign-flagged vessels are controlled by government agencies, and the remaining 6,345 foreign-flagged vessels are controlled by businesses. An analysis of a sample of the businesses controlling these vessels indicates that 48 percent are considered small.
- Compliance actions will consist of upgrading deficient CSMs and reporting lost or jettisoned cargo.
- Of the small entities in our sample with revenue information, 62 percent of them had an impact of less than 1 percent, and 28 percent had an impact within the 1 percent to 3 percent range.

The Regulatory Flexibility Act also requires an agency to conduct a final regulatory flexibility analysis (FRFA) unless it determines and certifies that a rule is not expected to have a significant impact on a substantial number of small entities. We are not able to certify that the interim rule will not have a significant economic impact on a substantial number of small entities. Therefore, we have prepared the following FRFA.

2. FRFA

The RFA establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration."

This FRFA was developed in accordance with Section 604(a) of the RFA. An FRFA must provide and/or address—

a. A statement of the need for, and objectives of, the rule;

b. A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the rule as a result of such comments;

c. The response of the agency to any comments filed by the Chief Counsel for Advocacy of the SBA in response to the rule, and a detailed statement of any change made to the interim rule as a result of the comments;

d. A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

e. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

f. A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the interim rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected;

g. For a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

a. A statement of the need for, and objectives of, the rule. The Coast Guard undertook this rulemaking to align U.S. regulations with the CSM requirements of SOLAS. The provisions of this rule also authorize recognized classification societies to review and approve CSMs on behalf of the Coast Guard, prescribe how other organizations can become CSM approval authorities, and prescribe when and how the loss or jettisoning of cargo must be reported. Enforcing those requirements should help prevent or mitigate the consequences of vessel cargo loss, and promote the Coast Guard maritime safety and stewardship missions.

Sections 2103 and 3306 of 46 U.S.C. provide the statutory basis for this rule. Section 2103 gives the Secretary of the department in which the Coast Guard is operating general regulatory authority to implement Subtitle II (Chapters 21 through 147) of Title 46, which includes statutory requirements in 46 U.S.C. Chapter 33 for inspecting the vessels to which this rule applies. Section 3306 gives the Secretary authority to regulate an inspected vessel's operation, fittings, equipment, appliances, and other items in the interest of safety. The Secretary's authority under both statutes has been delegated to the Coast Guard in Department of Homeland Security Delegation No. 0170.1(92)(a) and (b). Additionally, the United States is a party to SOLAS. Where SOLAS must be enforced through U.S. regulations, those regulations are authorized by E.O. 12234.

b. A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments. We received no specific comments in response to the IRFA. However, in response to one commenter's suggestion, when we finalize this interim rule we intend to make 33 CFR part 97, subpart A, applicable to all self-propelled vessels, regardless of tonnage, and not just to vessels of 500 gross tons or more. Also in response to comments, we have removed seagoing barges and other non-self-propelled vessels from the applicability of subpart A; this subpart now is applicable only to self-propelled vessels. In all other respects, the interim rule is substantively unchanged from our SNPRM proposals.

c. The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the interim rule as a result of the comments. We received no comments from the Chief Counsel for Advocacy of the SBA after the publication of the SNPRM.

d. A description of, and an estimate of, the number of small entities to which the proposed rule will apply or an explanation of why no such estimate is available. The applicable population consists of self-propelled vessels that carry any cargo other than solid or liquid bulk commodities and are—

- U.S.-flagged vessels engaged in international trade; or
- Foreign-flagged vessels that are in the U.S. trade.

Section VII.A.3, Affected Population, of this preamble presents an estimate of 6,436 vessels that will be subject to the interim rule. As described in Section VIII, Regulatory Analyses, of this preamble, we found that 83 vessels in the affected population were U.S.-flagged. For the cost analysis, we found that these vessels were currently in compliance with the CSM requirements. Also for the cost analysis, we assumed that compliance would continue throughout the 10-year forecast period and we continue with that assumption in this FRFA. The focus of this FRFA is on the 4,353 foreign-flagged vessels, which may be under the control of U.S. entities or foreign entities. Table 23 displays a break-out of this population by the type of entity that owns or operates these vessels.

TABLE 23—NON-U.S. VESSELS BY TYPE OF ENTITY

Entity type	Count	Percent
Business	6,345	99.87
Government	7	0.11
Not-for-Profit	1	0.02
Total	6,353	100.00

All the government entities exceed the threshold for being classified as a small entity, as they are either agencies of a foreign government or exceed the 50,000 population threshold. We excluded these government entities from the revenue impact analysis. The single not-for-profit entity is also deemed not small, as it is part of an international organization.

To analyze the potential impact on these businesses, we produced a random sample with a 95-percent confidence level and a confidence interval of 5 percent.[33] The resulting sample consisted of 288 businesses. We researched public and proprietary databases and company Web sites for the location of the company, entity type (subsidiary or parent company), primary line of business, employee size, revenue, and other information.[34] During the initial research, we found 1 entity that is now out of business and excluded it from the analysis. We found that 142 of the companies in our sample are based in countries other than the United States. There are another 78 entities for which we could not locate address information. Since they operate foreign-flagged vessels and we could not find location information in the Coast Guard databases and other sources, we inferred that they are operated by firms outside of the United States. Combining this information, we identified a total of 221 non-U.S. companies and excluded them from this revenue impact analysis. The population for the revenue impact analysis consists of the remaining 67 businesses from the working sample, and we found address information that locates all 67 of them in the United States.

We researched and compiled the employee size and revenue data for the 67 U.S. businesses and we compared this information to the SBA "Table of Small Business Size Standards" to determine if an entity is small in its primary line of business as classified in the North American Industry Classification System (NAICS).[35] We determined that 35 businesses exceeded the SBA small business size standards, and 32 businesses, or 48 percent of the sample, are small by the SBA standards. The information on location and size determination is summarized in Table 24.

TABLE 24—U.S. BUSINESS BY SIZE DETERMINATION

Entity type	Entities	Percent
Exceed the threshold ..	35	52.2
Below the threshold	32	47.8
Total	67	100.0

These 32 businesses that are below the SBA size thresholds are distributed among 16 NAICS classified industries. Table 25 lists the frequency, percentage, size standard, and size threshold of NAICS codes for the 32 small businesses found in the sample.

TABLE 25—NAICS CODES OF IDENTIFIED SMALL BUSINESSES

NAICS code	Industry	Count	Percent	Size standard	Size threshold
483111	Deep Sea Freight Transportation	12	37.5	Number of employees	500
488510	Freight Transportation Arrangement	5	15.6	Revenue	$14,000,000
487210	Scenic & Sightseeing Transportation, Water	2	6.3	Revenue	$7,000,000
423310	Lumber & Wood Merchant Whls	1	3.1	Number of employees	100
423860	Transportation Equipment and Supplies, Except Motor Vehicles.	1	3.1	Number of employees	100
424420	Packaged Frozen Food Merchant Wholesalers	1	3.1	Number of employees	100
424910	Farm Supplies Merchant Whls	1	3.1	Number of employees	100
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers.	1	3.1	Number of employees	100
441222	Boat Dealers	1	3.1	Revenue	$25,500,000
483113	Coastal and Great Lakes Freight Transportation.	1	3.1	Number of employees	500
484230	Specialized Freight Tracking Long Distance	1	3.1	Revenue	$14,000,000
488210	Support Activities for Rail Transportation	1	3.1	Revenue	500
488320	Marine Cargo Handling	1	3.1	Revenue	$25,500,000
493130	Farm Product Warehousing & Storage	1	3.1	Revenue	$14,000,000
532411	Commercial Air, Rail, and Water Transportation Equipment Rental and Leasing.	1	3.1	Revenue	$32,500,000
541618	Other Management Consulting Services	1	3.1	Revenue	$15,000,000
Total	....	32	99.7	....	....

We selected the two industries that appeared most frequently in the random sample of entities. Businesses from these two industries accounted for 17 entities, or 53 percent of the entities in the random sample. Therefore, we assume that approximately 53 percent of all entities affected by this regulation will be in one of these industries. A brief description of the two industries affected most by this rule follows.

- Deep Water Freight Transportation (483111): This industry comprises establishments primarily engaged in providing deep sea transportation of cargo to or from foreign ports.
- Freight Transportation Arrangement (488510): This industry comprises establishments primarily engaged in arranging transportation of freight between shippers and carriers. These establishments are usually known as freight forwarders, marine shipping agents, or customs brokers, and offer a combination of services spanning transportation modes.

e. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record. The compliance requirements of the rule consist of upgrading deficient CSMs and reporting lost or jettisoned cargo. Therefore, this rule calls for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Details on the burden estimate associated with this collection are available in Section VIII.D of this preamble.

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[33] We selected a statistical sample so we would not need to research and collect employee size and revenue information for the entire affected operator population. We selected the operators in the sample through a random number generator process available in most statistical or spreadsheet software.

[34] We used information and data from Cortera (*www.cortera.com*), Manta (*http://Manta.com*), and ReferenceUSA (*http://www.referenceusa.com*).

[35] The SBA lists small business size standards for industries described in the North American Industry Classification System. See *http://www.sba.gov/content/table-small-business-size-standards.*

As discussed in Section VIII.A, Regulatory Planning and Review, from 2011 through 2013, the Coast Guard conducted 14,358 vessel inspections and found problems relating to CSMs in only 9 instances, which amounts to approximately 0.1 percent of the foreign-flagged vessels whose CSMs were deficient. We anticipate that the owners or operators of these vessels will upgrade their CSMs to meet standards and comply with this rule. We do not have detailed descriptions on each of the deficiency cases. To estimate a cost for this compliance action, we apply the estimate of $7,625 to remedy a CSM, as used in the Regulatory Analysis.

For reporting lost or jettisoned cargo, we noted in Section VIII.A, Cost Discussions, that when one of these incidents occurs, the vessel staff already collects the needed information for company purposes. Thus, the only additional cost to the vessel is to report this information to the Coast Guard. We estimate the additional reporting will take 0.25 hours for the vessel's Master or other senior officer to compile and transmit the report to the Coast Guard. We estimate that the loaded wage rate for the Master or senior officer is $53.00 per hour. The cost of reporting is $13.25 (0.25 hours × $53 per hour).

As discussed in Section VIII.A, Regulatory Planning and Review, we adjusted the affected population to account for anticipated growth in container traffic. In our 10-year analysis, we estimate that the number of vessels that will need to upgrade their CSMs will be 4 in Years 1 through 5, and will increase to 6 in Year 10. We also accounted for this growth in container traffic in our estimate of lost or jettisoned cargoes. In Section VIII.A, Cost Discussions, we estimate that in the first year the rule becomes effective, 20 incidents of lost or jettisoned cargo will occur. We estimate that the affected population in that year consists of 6,436 U.S.- and foreign-flagged vessels, yielding an incident rate of 0.3 percent (20 incidents/6,436 vessels). To execute a revenue impact analysis, we posited that in any given year, each business would have one vessel that will need to upgrade its CSM and one vessel that will experienc an incident of lost or jettisoned cargo. Given these assumptions, the total annual compliance cost for any company is $7,638.25, as shown in Table 26.

TABLE 26—ANNUAL COMPLIANCE COST FOR REVENUE IMPACT ANALYSIS

Cost	Loaded wage	Hours	Total cost
Upgrading 1 CSM	N/A	N/A	$7,625
Reporting 1 hazardous condition	$53	0.25	13.25
Total			7,638.25

For each business in our sample with revenue data, we calculated the impact as the assumed cost of $7,638.25 as a percentage of that business's annual revenue. This produced a range of potential revenue impacts across the sample. Table 27 presents the impact data in ranges of less than 1 percent, 1 to 3 percent, 3 to 5 percent, and greater than 5 percent. As shown in this table, for approximately 62 percent of the companies, the revenue impact is less than 1 percent of annual revenue, and for approximately 28 percent of the companies, the revenue impact is between 1 percent and 3 percent.

TABLE 27—ESTIMATED REVENUE IMPACT ON SMALL BUSINESSES

Revenue impact class	Count	Percentage of companies
Less than 1%	20	62.5
1% to 3%	9	28.1
3% to 5%	1	3.1
Less than 5%	2	6.3
Total	32	100.0

As shown in Table 22, the highest cost to industry in any one year on an undiscounted basis is $114,786, which occurs in Year 10.

The revenue impact analysis indicates that 62 percent of the affected population will have an impact of less than 1 percent and the other 28 percent will have an impact between 1 percent and 3 percent.

f. A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the interim rule. Also, include a description explaining why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected. Our cost estimate for the reporting of the lost or jettisoned cargo was based on information indicating that the vessel's crew already collects the needed information for business reasons. The only additional step required by this interim rule is to prepare the message to the Coast Guard, and that message can be delivered by a variety of electronic media. Thus, this interim rule minimizes the burden to a vessel's crew in order to provide additional information to the Coast Guard to enhance its execution of its maritime environmental protection mission.

For CSMs, this interim rule is based solely on current requirements contained in SOLAS and current Coast Guard guidance. Our regulatory analysis indicates that 99 percent of the subject vessels currently comply with these requirements. This rule enhances the Coast Guard's maritime safety mission without adding any new requirements to vessel owners and operators.

Alternatives were considered in this interim rule and are discussed in section VIII.A, Cost Discussions, of this preamble. Alternatives include various ways to apply the requirements to prepare and implement CSMs to U.S.-flagged vessels in coastwise trade. However, we concluded that standards developed for international trade cannot be economically justified for vessels operating only domestically at this time. Therefore, the focus of this interim rule is exclusively on vessels in international trade.

g. For a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities. The Coast Guard is not a covered agency.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we offered to assist small entities in understanding this rule so that they could better evaluate its effects on them and participate in the rulemaking. The

Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This rule calls for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), "collection of information" comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collection, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for preparing and reporting for the development of a CSM, revising a CSM, notification of other hazardous conditions, and notification of lost or jettisoned cargo.

This collection of information applies to rulemaking procedures regarding CSMs. Specific areas covered in this information collection include 33 CFR part 97, "Cargo Securing Manuals;" 33 CFR part 160, "Ports and Waterways Safety-General;" and 46 CFR part 97, "Operations." This rule will align the CFR with SOLAS.

TITLE: Cargo Securing Manuals.

OMB CONTROL NUMBER: 1625–0122.

SUMMARY OF COLLECTION OF INFORMATION: The rule will add a new part 97, "Cargo Securing Manuals" to chapter 33 of the CFR. The collection of information burden for CSMs derives from one of these three events:

- A SOLAS container vessel built after the rule becomes effective will need to develop and implement a CSM. The new vessel will need an approved CSM.
- If a vessel changes its type, the CSM must be revised. An example of a type change is when a general break-bulk carrier is modified to become a containership.
- If an existing vessel either changes 15 percent of its cargo securing systems or more than 15 percent of its portable securing devices, the CSM must be revised.

Additionally, this interim rule will impose burdens for the notification of hazardous conditions. Currently, these notifications are made via VHS radio, satellite radio, cell phones, and other forms of electronic communication. The rule specifically allows for electronic communications, and we anticipate this will continue to be how the notifications are transmitted.

Need for Information: Vessel owners or operators need to develop and implement CSMs to fulfill international safety standards established by SOLAS. The Coast Guard needs timely information on hazardous conditions to carry out its missions relating to protecting vessels, their crews and passengers, and the environment.

Proposed use of Information: For new and modified CSMs, Coast Guard-authorized third-party organizations will review these CSMs and, if they are found to be acceptable, approve them. The Coast Guard will use the information from the notification of hazardous conditions to inform other vessel operators or waterway users of the situation and initiate any needed measures to reduce or eliminate the hazard. These actions will lead to a reduction of vessel casualties and pollution.

Description of Respondents: There are three groups of respondents impacted by this interim rule:

- Owners or operators of U.S.-flagged vessels that will need to submit new or revised CSMs to the recognized classification societies.
- Recognized classification societies and other approved third-party organizations that will review the CSMs on behalf of the Coast Guard.
- The operators of vessels that will be required to report hazardous conditions.

Number of Respondents: We estimate that there will be 276 respondents affected annually by the CSM requirements. The total is divided into these three classes: (1) 83 for new CSMs; (2) 9 for revisions to existing CSMs; and (3) 184 notifications of hazardous conditions, which include lost or jettisoned cargo and other incidents. Table 28 describes the calculations for developing the estimates of each requirement relating to the CSM plans.

TABLE 28—ESTIMATES OF NUMBER OF RESPONDENTS

Class	Requirement	Description	Count	Total
CSM	Develop CSM, new vessel	83 in Year 1	83	
	Revise CSM, change in vessel type.	MISLE data shows none of the affected vessels have changed vessel type from 2001–2012.	0	
	Revise CSM, replace CSM systems or equipment.	Annual rate of 11.3% from information supplied by an approved organization. Applied to U.S. population (see Table 3), (83 × 11.3%).	9	
CSM Total				92
Notifications	Notifications of hazardous condition.	From MISLE, average of 2009–2011 notifications	180	
	Notifications of lost or jettisoned cargo.	U.S. notifications, Table 8, year 10	4	
Notifications Total				184
Grand Total				276

Frequency of Response: A CSM is valid indefinitely, provided it does not meet any of the conditions for a revision. The reporting of hazardous conditions occurs as needed. In the subsequent "Number of Respondents" section, we present annual estimates of the reports.

Burden of Response: The burden hours per requirement is estimated and shown below in Table 29.

TABLE 29—ANNUAL BURDEN HOURS PER REQUEST

Requirement	Hours	Notes
Develop new CSM	48	8 hours to survey the vessel and 40 hours to draft the CSM.
Revise CSM—change in vessel type	48	8 hours to survey the vessel and 40 hours to draft the CSM.
Revise CSM—change in cargo securing systems or equipment	20	20 hours to revise the existing CSM.
Notification of hazardous condition	0.25	0.25 hours for vessel crew to prepare and transmit the notice.
Notification of lost of jettisoned cargo	0.25	0.25 hours for vessel crew to prepare and transmit the notice.

Estimated Total Annual Burden: We estimate that the total annual burden to industry will be 4,210 hours. Table 30 displays the total burden hours for each request:

TABLE 30—TOTAL ANNUAL BURDEN HOURS

Requirement	Hours
Develop new CSM	3,984
Revise CSM, change in vessel type	0
Revise CSM, change in cargo securing systems or equipment	180
Notification of hazardous condition	45
Notification of lost or jettisoned cargo	1
Total	4,210

Note: Total does not exactly sum due to independent rounding.

Reason For Change: This interim rule will require collections of information regarding these two activities: (1) Development or revision of a CSM; and (2) notification of hazardous conditions, including lost or jettisoned cargo.

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that we consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number.

This interim rule will impose new information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we will submit these new information collection requirements to OMB for its review. Notice of OMB information collection will be published in a future **Federal Register** notice.

E. Federalism

A rule has implications for federalism under E.O. 13132, Federalism, if it has substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under E.O. 13132 and have determined that it does not have implications for federalism. Our analysis follows.

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled, now, that all of the categories covered in 46 U.S.C. 3306, 3703, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels), as well as the reporting of casualties and any other category in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, are within the field foreclosed from regulation by the States. (See the decision of the Supreme Court in the consolidated cases of *United States* v. *Locke* and *Intertanko* v. *Locke.)*[36]

This rule on cargo securing falls into the category of vessel operation. Because the States may not regulate within this category, the rule is consistent with the principles of federalism and preemption requirements in E.O. 13132.

Additionally, 33 CFR 160.215 is promulgated under the authority of the Ports and Waterways Safety Act, Title I, and therefore, under the principles of *Locke,* preempts any conflicting or similar State regulations.[37] The *Locke* court also held that Congress preempted the field of marine casualty reporting. The Coast Guard does not believe that this proposed amendment to an existing reporting requirement would be preemptive of any existing State or local regulations or requirements. However, any prospective State requirement for information reporting that conflicts with or is similar to the one proposed in this interim rule would be inconsistent with the federalism principles enunciated in *Locke* and therefore would be preempted.

The Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, E.O. 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this interim rule has implications for federalism under E.O. 13132, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

F. Unfunded Mandates Reform Act

Section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

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[36] 529 U.S. 89, 120 S.Ct. 1135 (March 6, 2000).

[37] *See* our statement to this effect, 68 FR 9537 at 9543 (Feb. 28, 2003).

K. Energy Effects

We have analyzed this rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule uses technical standards other than voluntary consensus standards. It incorporates two circulars and one resolution adopted by arms of the International Maritime Organization, an international organization under United Nations auspices, of which the United States is a member state. The two circulars describe in detail how a vessel's owner or operator may comply with CSM requirements contained in the International Convention for the Safety of Life at Sea. The resolution provides guidelines for third parties acting on behalf of a government agency like the Coast Guard.

All three documents may be obtained from the IMO using the address given in the regulatory text for new 33 CFR 97.110.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2–1, paragraph (34)(d) and under section 6(a) of the "Appendix to National Environmental Policy Act: Coast Guard Procedures for Categorical Exclusions, Notice of Final Agency Policy" (67 FR 48244, July 23, 2002). This rule involves regulations which concern documentation and equipping of vessels, as well as regulations concerning vessel operation safety standards. An environmental analysis checklist and a categorical exclusion are available in the docket where indicated under **ADDRESSES**.

List of Subjects

33 CFR Part 97

Cargo stowage and securing, Cargo vessels, Hazardous materials, Incorporation by reference, Reporting and recordkeeping requirements.

33 CFR Part 160

Administrative practice and procedure, Harbors, Hazardous materials transportation, Marine safety, Navigation (water), Personally identifiable information, Reporting and recordkeeping requirements, Seamen, Vessels, Waterways.

46 CFR Part 97

Cargo vessels, Marine safety, Navigation (water), Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR chapter I and 46 CFR part 97 as follows:

Title 33—Navigation and Navigable Waters

■ 1. Add part 97 to subchapter F to read as follows:

PART 97—RULES FOR THE SAFE OPERATION OF VESSELS, STOWAGE AND SECURING OF CARGOES

Subpart A—Cargo Securing Manuals

Sec.

97.100 Applicability—Electronic documentation.
97.105 Definitions.
97.110 Incorporation by reference.
97.115 Reporting lost or jettisoned cargo.
97.120 Cargo securing manuals.
97.121–97.199 [Reserved]
97.200 Cargo securing manual (CSM) approval for U.S.-flagged vessels on international voyages.
97.205 Requirements for amending an approved cargo securing manual (CSM).
97.210 Appeals.
97.211–97.299 [Reserved]
97.300 Authorized cargo securing manual (CSM) approval authorities.
97.305 Requests for authorization to act as cargo securing manual (CSM) approval authority.
97.310 Criteria for authorization.
97.315 Requirements for authorized approval organizations.
97.320 Revocation of authorization.

Subpart B—[Reserved]

Authority: 46 U.S.C. 2103, 3306; E.O. 12234; Department of Homeland Security Delegation No. 0170.1(92)(a) and (b).

PART 97—RULES FOR THE SAFE OPERATION OF VESSELS, STOWAGE AND SECURING OF CARGOES

Subpart A—Cargo Securing Manuals

§ 97.100 Applicability—Electronic documentation.

(a) This subpart applies to—

(1) A self-propelled cargo vessel of 500 gross tons or more, on an international voyage, that must comply with Chapter VI/5.6 or Chapter VII/5 of the International Convention for the Safety of Life at Sea, 1974 as amended (SOLAS), that does not solely carry liquid or solid cargoes in bulk, and that is either a U.S.-flagged self-propelled cargo vessel, or a foreign-flagged self-propelled cargo vessel that is operating in waters subject to the jurisdiction of the United States;

(2) A U.S.-flagged self-propelled cargo vessel that chooses to have this subpart applied to it by submitting a cargo securing manual for approval in accordance with § 97.200(a)(3);

(3) A foreign-flagged self-propelled cargo vessel of 500 gross tons or more on an international voyage from a country that is not a signatory to SOLAS, that would otherwise be required to comply with Chapter VI/5.6 or Chapter VII/5 of SOLAS, that does not solely carry liquid or solid cargoes in bulk, and that is operating in waters subject to the jurisdiction of the United States; and

(4) Any organization applying to be selected as a cargo securing manual approval authority.

(b) This subpart does not apply to a vessel owned by the Maritime Administration that is part of the Ready Reserve Force or the title of which is vested in the United States and which is used for public purposes only.

(c) Any manual, letter, request, appeal, or ruling required by this subpart may be provided or submitted in electronic form or in printed form.

§ 97.105 Definitions.

As used in this subpart—

Approval authority means a CSM approval authority, as that term is defined in this section.

Cargo means the goods or merchandise conveyed in a vessel, and includes, but is not limited to, cargo that can be measured as a "cargo unit" as that term is used in the International Maritime Organization's Code of Safe Practice for Cargo Stowage and Securing, 2003 edition: "a vehicle, container, flat, pallet, portable tank, packaged unit, or any other entity, etc., and loading equipment, or any part thereof, which belongs to the ship but is not fixed to the ship . . ."; but it does not include other vessel equipment or the incidental personal possessions of persons on board the vessel.

Cargo safe access plan (CSAP) means a plan included in the cargo securing manual that provides detailed information on safe access for persons engaged in work connected with cargo stowage and securing on ships that are specifically designed and fitted for the purpose of carrying containers.

Cargo securing manual (CSM) means an electronic or printed manual developed to meet the requirements of SOLAS and this subpart and that is used by the master of a vessel to properly stow and secure cargoes on the vessel for which it is developed.

Cargo securing manual approval authority or *CSM approval authority* means an organization that meets the requirements of this subpart, and that the Commandant has authorized to conduct certain actions and issue electronic or printed approval letters on behalf of the United States.

Captain of the Port (COTP) means the U.S. Coast Guard officer as described in 33 CFR 6.01–3.

Commandant, except as otherwise specified, means the Chief, Office of Operating and Environmental Standards, whose address is Commandant (CG–OES), 2703 Martin Luther King, Jr. Avenue SE., Stop 7509, Washington, DC 20593–7509 and whose telephone number is 202–372–1404.

Container means an article of transport equipment described in 49 CFR 450.3.

Container vessel means a vessel specifically designed and fitted for the purpose of carrying containers.

International voyage means a voyage between a port or place in one country (or its possessions) and a port or place in another country.

§ 97.110 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection by contacting Mr. Ken Smith of the Coast Guard's Vessel and Facility Operating Standards Division, Commandant (CG–OES–2); telephone 202–372–1413, email *Ken.A.Smith@uscg.mil,* and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) *International Maritime Organization (IMO), Publications Section,* 4 Albert Embankment, London, SE1 7SR, United Kingdom, +44(0)20 7735 7611, *http://www.imo.org.*

(1) MSC.1/Circ.1352, Amendments to the Code of Safe Practice for Cargo Stowage and Securing (CSS Code), June 30, 2010 (Maritime Safety Committee Circular), IBR approved for § 97.120(b).

(2) MSC.1/Circ. 1353/Rev.1, Revised Guidelines for the Preparation of the Cargo Securing Manual, December 15, 2014 (Maritime Safety Committee Circular), IBR approved for § 97.120(a).

(3) Resolution A.739(18) (Res.A.739(18)), Guidelines for the Authorization of Organizations Acting on Behalf of the Administration, November 22, 1993 (Assembly Resolution), IBR approved for § 97.310(a).

§ 97.115 Reporting lost or jettisoned cargo.

(a) In the event a vessel loses or jettisons at sea any cargo described in paragraph (b) of this section, it must comply with the immediate notification requirements of 33 CFR 160.215, and if the cargo contains hazardous material as defined in paragraph (c) of this section, the vessel must also report it as soon as possible in accordance with 49 CFR 176.48.

(b) The cargo to which this section applies includes any container and any other cargo the loss or jettisoning of which could adversely affect the safety of any vessel, bridge, structure, or shore area or the environmental quality of any port, harbor, or navigable waterway of the United States.

(c) As used in this section, "hazardous material" means a substance or material designated by the Secretary of Transportation as capable of posing an unreasonable risk to health, safety, and property when transported in commerce. The term includes hazardous substances, hazardous wastes, marine pollutants, and elevated temperature materials as defined in 49 CFR 171.8, materials designated as hazardous under the provisions of 49 CFR 172.101, and materials that meet the defining criteria for hazard classes and divisions in 49 CFR part 173.

§ 97.120 Cargo securing manuals.

(a) Any vessel to which this subpart applies must have a cargo securing manual (CSM) on board that has been approved by the government of the country whose flag the vessel is entitled to fly; and a CSM approved after June 30, 2010, must, at a minimum, meet the guidelines in MSC.1/Circ. 1353/Rev.1, (incorporated by reference, see 33 CFR 97.110).

(b) A container vessel with a keel laid on or after January 1, 2015, must include a cargo safe access plan that, at a minimum, meets the guidelines in MSC.1/Circ.1352, Annex 14, Guidance on Providing Safe Working Conditions for Securing of Containers on Deck (incorporated by reference, see 33 CFR 97.110).

(c) While operating in waters under the jurisdiction of the United States, the Coast Guard may board any vessel to which this subpart applies to determine that the vessel has the document(s) required by paragraph (a) of this section on board. Any foreign-flagged vessel found not to be in compliance with paragraph (a) of this section may be detained by order of the Captain of the Port at the port or terminal where the noncompliance is found until the COTP determines that the vessel can go to sea without presenting an unreasonable threat of harm to the port, the marine environment, the vessel, or its crew.

§§ 97.121–97.199 [Reserved]

§ 97.200 Cargo securing manual (CSM) approval for U.S.-flagged vessels on international voyages.

(a) Owners of U.S.-flagged vessels on international voyages must have Cargo Securing Manuals (CSMs) approved in accordance with this part.

(1) An applicant for CSM approval may be the owner or operator of the vessel, or a person acting on the owner or operator's behalf.

(2) The Commandant is responsible for overseeing and managing the review and approval of CSM approval authority applications and providing an up-to-date list of organizations authorized to act under this subpart, which is available at *http://www.uscg.mil/hq/cg5/cg522/cg5222,* or by requesting it in writing from the Commandant and

enclosing a self-addressed, stamped envelope.

(3) The applicant must submit two dated copies of a CSM that meets the requirements of this subpart to a CSM approval authority for review and approval. If any amendments are submitted, they must be dated. The CSM must include a "change page" document to ensure continuous documentation of amendments made and the dates they were completed.

(4) The approval authority will retain one copy of the CSM for its records.

(b) If the approval authority completes the review process and approves the CSM, the approval authority will provide a CSM approval letter on its letterhead, containing—

(1) Date of CSM approval;

(2) A subject line reading: "APPROVAL OF CARGO SECURING MANUAL (AMENDMENT—if applicable) FOR THE M/V ____, OFFICIAL NUMBER ____";

(3) The following statement: "This is to certify that the Cargo Securing Manual (Amendment—if applicable) dated ____ for the M/V ____, Official Number ____, has been approved on behalf of the United States. The Cargo Securing Manual (Amendment—if applicable) was reviewed for compliance with Maritime Safety Committee Circular 1353 (MSC.1/Circ. 1353/Rev.1) for content, and correctness of the calculations on which the approval is based. This approval letter is to be kept with the Cargo Securing Manual, as proof of compliance with regulations VI/5.6 and VII5 of the 2004 amendments to the International Convention for the Safety of Life at Sea (SOLAS) 1974.";

(4) Signature of the approval authority official responsible for review and approval of the CSM; and

(5) The approval authority's seal or stamp.

(c) If the approval authority completes the review process and disapproves the CSM, the approval authority will provide a letter on its letterhead, containing—

(1) Date of CSM disapproval; and

(2) Explanation of why the CSM was disapproved and what the submitter must do to correct deficiencies.

(d) The submitter of a disapproved CSM may resubmit the CSM with amendments for further review, either to correct deficiencies noted by the approval authority or to expand the CSM to fully meet the requirements of this part.

(e) The original copy of the CSM approval letter must be kept with the approved CSM and its amendments, together with supporting documents and calculations used in granting the approval, on board the vessel for review by Coast Guard personnel upon request.

§ 97.205 Requirements for amending an approved cargo securing manual (CSM).

Resubmission and re-approval by a CSM approval authority are required after any of the following events occurs:

(a) Reconfiguration of a vessel from one type of cargo carriage to another (*e.g.*, a general break-bulk cargo vessel reconfigured to a container or a roll-on/roll-off vessel).

(b) Reconfiguration or replacement of 15 percent or more of the vessel's fixed cargo securing or tie-down systems with different types of devices or systems.

(c) Replacement of 15 percent or more of the vessel's portable cargo securing devices, with different types of devices for securing the cargo not already used aboard the vessel (*e.g.*, wire lashings replaced with turnbuckles or chains).

§ 97.210 Appeals.

(a) A vessel owner or operator, or person acting on their behalf, who disagrees with a decision of a CSM approval authority may submit a written appeal to the approval authority requesting reconsideration of information in dispute. Within 30 days of receiving the appeal, the approval authority must provide the submitter with a final written ruling on the request, with a copy to the Commandant.

(b) A submitter who is dissatisfied with the approval authority's final written ruling may appeal directly to the Commandant. The appeal must be made in writing and include the documentation and supporting evidence the submitter wants to be considered, and may ask the Commandant to stay the effect of the appealed decision while it is under review by the Commandant.

(c) The Commandant will make a decision on the appeal and send a formal response to the submitter and a copy to the approval authority. The Commandant's decision will constitute final agency action on the appeal request.

§§ 97.211–97.299 [Reserved]

§ 97.300 Authorized cargo securing manual (CSM) approval authorities.

The following organizations are authorized to act on behalf of the United States for the review and approval of CSMs:

(a) Any recognized classification society to which the Coast Guard has delegated issuance of a Cargo Ship Safety Equipment Certificate in accordance with 46 CFR 8.320(b)(4). A list of these organizations can be found at *www.uscg.mil/hq/cg5/cg522/cg5222* in the "Summary of Authorizations" link.

(b) The National Cargo Bureau, Inc., 17 Battery Place, Suite 1232, New York, NY 10004–1110, 212–785–8300, *http://www.natcargo.org*.

§ 97.305 Requests for authorization to act as cargo securing manual (CSM) approval authority.

An organization seeking authorization as a CSM approval authority must make a request to the Commandant for authorization. The request must include, in writing, the items listed in this section or as otherwise specified by the Commandant.

(a) A certified copy of the organization's certificate of incorporation or partnership on file with a U.S. State, including the name and address of the organization, with written statements or documents which show that—

(1) The organization's owners, managers, and employees are free from influence or control by vessel shipbuilders, owners, operators, lessors, or other related commercial interests as evidenced by past and present business practices;

(2) The organization has demonstrated, through other related work, the capability to competently evaluate CSMs for completeness and sufficiency according to the requirements of SOLAS and this part;

(3) The organization has an acceptable degree of financial security, based on recent audits by certified public accountants over the last 5 years; and

(4) The organization maintains a corporate office in the United States that has adequate resources and staff to support all aspects of CSM review, approval, and recordkeeping.

(b) A listing of the names of the organization's principal executives, with titles, telephone, and telefax numbers.

(c) A written general description of the organization, covering the ownership, managerial structure, and organization components, including any directly affiliated organizations, and their functions utilized for supporting technical services.

(d) A written list of technical services the organization offers.

(e) A written general description of the geographical area the organization serves.

(f) A written general description of the clients the organization is serving, or intends to serve.

(g) A written general description of similar work performed by the organization in the past, noting the amount and extent of such work performed within the previous 3 years.

(h) A written listing of the names of full-time professional staff employed by the organization and available for technical review and approval of CSMs including—

(1) Naval architects and naval engineers, with copies of their professional credentials, college degrees, and specialized training certificates;

(2) Merchant mariners with Coast Guard-issued credentials, with a summary of their working experience on board cargo vessels (including vessel tonnage and types of cargo); and

(3) Written proof of staff competence to perform CSM review and approval, evidenced by detailed summaries of each individual's experience (measured in months) during the past 5 years of evaluating maritime cargo securing systems. Experience summaries must be documented on company letterhead and endorsed by a company executive who has had direct observation of the individual and quality of his or her work product.

(j) A complete description of the organization's internal quality control processes, including written standards used by the organization to ensure consistency in CSM review and approval procedures by qualified professionals.

(k) A description of the organization's training program for assuring continued competency of professional employees performing CSM review and approval who are identified in the application.

(l) Evidence of financial stability over the past 5-year period, such as financial reports completed independently by certified public accountants.

(m) A list of five or more business references, including names, addresses, and telephone numbers of principal executives, who can attest to the organization's competence within the past 2 years.

(n) A statement to the Coast Guard that gives its officials permission to inspect the organization's facilities and records of CSM review and approval on behalf of the United States at any time with reasonable advance notice.

(o) Any additional information the organization deems to be pertinent.

§ 97.310 Criteria for authorization.

(a) The Commandant will evaluate the organization's request for authorization and supporting written materials, looking for evidence of—

(1) The organization's clear assignment of management duties;

(2) Ethical standards for managers and cargo securing manual (CSM) reviewers;

(3) Procedures for personnel training, qualification, certification, and re-qualification that are consistent with recognized industry standards;

(4) Acceptable standards available for the organization's internal auditing and management review;

(5) Recordkeeping standards for CSM review and approval;

(6) Methods used to review and certify CSMs;

(7) Experience and knowledge demonstrating competency to evaluate CSMs for completeness and sufficiency according to the requirements of SOLAS;

(8) Methods for handling appeals; and

(9) Overall procedures consistent with Res.A.739(18), (incorporated by reference, see § 97.110).

(b) After a favorable evaluation of the organization's request, the Commandant may arrange to visit the organization's corporate and port offices for an on-site evaluation of operations.

(c) When a request is approved, the organization and the Coast Guard will enter into the written agreement provided for by 33 CFR 97.315. If the request is not approved, the Commandant will give the organization a written explanation, and the organization may resubmit its request if it corrects any noted deficiencies.

§ 97.315 Requirements for authorized approval organizations.

Approved organizations will enter into a written agreement with the Coast Guard that specifies—

(a) The period the authorization is valid;

(b) Which duties and responsibilities the organization may perform and what approval letters it may issue on behalf of the U.S.;

(c) Reports and information the organization must send to the Commandant;

(d) Actions the organization must take to renew the agreement when it expires; and

(e) Actions the organization must take if the Commandant revokes authorization pursuant to 33 CFR 97.320.

§ 97.320 Revocation of authorization.

The Commandant may revoke a cargo securing manual (CSM) approval authority's authorization and remove it from the list of CSM approval authorities if it fails to maintain acceptable standards. For the purposes of 46 CFR subpart 1.03, such a revocation would be treated as involving the recognition of a classification society and could be appealed pursuant to 46 CFR 1.03–15(h)(4). Upon revocation, the former approval authority must send written notice to each vessel owner whose CSM it approved. The notice must include the current list of CSM approval authorities and state—

(a) That its authorization as a CSM approval authority has been revoked;

(b) The Coast Guard's explanation for the revocation; and

(c) That the vessel's CSM remains valid as long as amendments have not been completed which require it to be re-approved pursuant to 33 CFR 97.200 or 97.205.

Subpart B—[Reserved]

PART 160—PORTS AND WATERWAYS SAFETY—GENERAL

■ 2. The authority citation for part 160 continues to read as follows:

Authority: 33 U.S.C. 1223, 1231; 46 U.S.C. Chapter 701; Department of Homeland Security Delegation No. 0170.1. Subpart C is also issued under the authority of 33 U.S.C. 1225 and 46 U.S.C. 3715.

■ 3. Revise § 160.215 to read as follows:

§ 160.215 Notice of hazardous conditions.

(a) Whenever there is a hazardous condition either on board a vessel or caused by a vessel or its operation, the owner, agent, master, operator, or person in charge must immediately notify the nearest Coast Guard Sector Office or Group Office, and in addition submit any report required by 46 CFR 4.05–10.

(b) When the hazardous condition involves cargo loss or jettisoning as described in 33 CFR 97.115, the notification required by paragraph (a) of this section must include—

(1) What was lost, including a description of cargo, substances involved, and types of packages;

(2) How many were lost, including the number of packages and quantity of substances they represent;

(3) When the incident occurred, including the time of the incident or period of time over which the incident occurred;

(4) Where the incident occurred, including the exact or estimated location of the incident, the route the ship was taking, and the weather (wind and sea) conditions at the time or approximate time of the incident; and

(5) How the incident occurred, including the circumstances of the incident, the type of securing equipment that was used, and any other material failures that may have contributed to the incident.

Title 46—Shipping

PART 97—OPERATIONS

■ 3. The authority citation for part 97 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3306, 6101; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757; 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 4. Add § 97.12–10 to read as follows:

§ 97.12–10 Cargo securing manuals.

Each U.S.-flagged vessel that must comply with Chapter VI/5.6 or Chapter VII/5 of the International Convention for the Safety of Life at Sea, 1974 as amended must have on board a cargo securing manual that meets the requirements of 33 CFR part 97.

Dated: April 28, 2016.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2016–10725 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0090]

RIN 1625–AA09

Drawbridge Operation Regulation; Youngs Bay, Astoria, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the operating schedule that governs the Oregon State (Old Youngs Bay) highway bridge, mile 2.4, across Youngs Bay foot of Fifth Street at Astoria, OR. The Oregon Department of Transportation (ODOT) requested to change the operating schedule of the Old Youngs Bay Bridge for work on both bascule lifts. This change will allow ODOT to operate the double bascule draw in single leaf mode, one lift at a time, which will reduce the vertical clearance of the non-operable half of the span by five feet.

DATES: This temporary final rule is effective from 12 a.m. on June 16, 2016 through 11:59 p.m. on October 31, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0090 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call or email Steven M. Fischer, Bridge Administrator, Thirteenth Coast Guard District Bridge Program Office, telephone 206–220–7282; email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of Proposed Rulemaking
§	Section Symbol
U.S.C.	United States Code
ODOT	Oregon State Department of Transportation
TFR	Temporary Final Rule

II. Background, Purpose and Legal Basis

The Coast Guard is issuing this temporary final rule (TFR) without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because to do so would be unnecessary. This deviation is already in place and waterway users are already acting in accordance with the schedule with no actual or anticipated impacts. Additionally, in response to the initial request from the ODOT, the Coast Guard published a notice of deviation on February 3, 2016, 81 FR 6758, which temporarily changed the operating schedule of the Old Youngs Bay Bridge through June 15, 2016. The Coast Guard contacted known waterway users who indicated such a deviation would have no significant impact. Therefore, it is unnecessary to provide an opportunity for notice and comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The ODOT owns and operates the Old Youngs Bay Bridge in accordance with 33 CFR 117.899(b). This bridge provides a vertical clearance approximately 19 feet above mean high water when in the closed-to-navigation position. ODOT is conducting bridge repairs, which are scheduled to be complete on October 31, 2016. In order to facilitate bridge repairs, one half of the double bascule bridge will have a containment system installed on the non-opening half of the span. This containment system will reduce the vertical clearance of the bridge by 5 feet, or 14 feet above mean high water. Both the previous notice of temporary deviation and this TFR allow the drawtender to open only half the draw span in single leaf mode.

Marine traffic on Youngs Bay consists of vessels ranging from small pleasure craft, sailboats, small tribal fishing boats, and commercial tug and tow, and mega yachts.

IV. Discussion of the Rule

We are amending 33 CFR 117.899 to indicate that half of the double bascule span of the Youngs Bay Bridge will be opened instead of both spans once notice has been provided to the drawtender at the Lewis and Clark River Bridge. The draw span will be operable from 7 a.m. to 5 p.m. on weekdays and from 8 a.m. to 4 p.m. on weekends. This amendment will be in effect from 12 a.m. on June 16, 2016 through 11:59 p.m. on October 31, 2016, after which the bridge will be able to open both spans as before. The TFR is necessary to accommodate extensive maintenance and restoration efforts on the Old Youngs Bay Bridge. The TFR will allow construction workers to complete bridge and highway upgrades before winter, while having minimal impact on maritime navigation.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders (E.O.(s)) related to rulemaking. Below we summarize our analyses based on these statutes and E.O.(s), and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O. 12866 and E.O. 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget. This regulatory action determination is based on the ability of the Old Youngs Bay Bridge to open half the span on signal.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule would not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.899, from 12 a.m. on June 16, 2016 through 11:59 p.m. on October 31, 2016, suspend paragraph (b) and add a paragraph (d).

The addition reads as follows:

§ 117.899 Youngs Bay and Lewis and Clark River.

* * * * *

(d) The draw of the Oregon State (Old Youngs Bay) highway bridge, mile 2.4, across Youngs Bay foot of Fifth Street, shall open half of the double bascule span on signal for the passage of vessels, if at least one half-hour notice is given to the drawtender, at the Lewis and Clark River Bridge by marine radio, telephone, or other suitable means from 7 a.m. to 5 p.m. Monday through Friday and from 8 a.m. to 4 p.m. Saturday and Sunday through October 31, 2016. At all other times, including all Federal holidays, but Columbus Day, at least a two-hour notice by telephone is required. The opening signal is two prolonged blasts followed by one short blast.

R.T. Gromlich,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2016–10772 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0177]

RIN 1625–AA00

Safety Zone: San Francisco State Graduation Fireworks Display, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters near AT&T Park in San Francisco, CA in support of the San Francisco State University Graduation Fireworks Display on May 28, 2016. This safety zone is established to ensure the safety of mariners and spectators from the dangers associated with the pyrotechnics. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or their designated representative.

DATES: This rule is effective from 1 p.m. through 10 p.m. on May 28, 2016.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2016–0177. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

APA	Adminstrative Procedure Act
COTP	Captain of the Port
DHS	Department of Homeland Security
E.O.	Executive Orders
FR	Federal Register
COTP	Captain of the Port
NEPA	National Environmental Policy Act of 1969
NOAA	National Oceanic and Atmospheric Administration
PATCOM	Patrol Commander
RFA	Regulatory Flexibility Act of 1980
TFR	Temporary Final Rule

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Because of the dangers posed by the pyrotechnics used in this fireworks display, the safety zone is necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event in order to minimize potential danger to the public during the event. However, the Coast Guard received the information about the fireworks display on February 26, 2016. There is not enough time to complete the rulemaking process before the fireworks display is scheduled to occur.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For these same reasons, the Coast Guard finds good cause for implementing this rule less than thirty days before the effective date of the rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish safety zones.

The San Francisco State University Graduation will feature a finale fireworks display on May 28, 2016, near AT&T Park in San Francisco, CA in approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83) as depicted in National Oceanic and Atmospheric Administration (NOAA) Chart 18650. During the loading, transit, and arrival of the fireworks barge and until the start of the fireworks display, the temporary safety zone applies to the navigable waters around and under the fireworks barge within a radius of 100 feet. From 1 p.m. until 5 p.m. on May 28, 2016, the fireworks barge will be loading at Pier 50 in San Francisco, CA. The fireworks barge will remain at Pier 50 until the start of the transit. From 8 p.m. until 8:30 p.m. on May 28, 2016, the loaded fireworks barge will transit from Pier 50 to the launch site near AT&T Park in San Francisco, CA in approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83), where it will remain until the commencement of the fireworks display. Prior to the commencement of the 10-minute fireworks display, at 9:30 p.m. on May 28, 2016, the safety zone will expand to encompass the navigable waters within 700 feet of approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83). The fireworks display is meant for entertainment purposes. This restricted area around the fireworks launch site is necessary to protect spectators, vessels, and other property from the hazards associated with pyrotechnics.

IV. Discussion of the Final Rule

The proposed safety zone will encompass the navigable waters around the barge near AT&T Park in San Francisco, CA. During the loading, transit, and arrival of the fireworks barge and until the start of the fireworks display, the temporary safety zone applies to the navigable waters around and under the fireworks barge within a radius of 100 feet. From 1 p.m. until 5 p.m. on May 28, 2016, the fireworks barge will be loading at Pier 50 in San Francisco, CA. The fireworks barge will remain at Pier 50 until the start of the transit. From 8 p.m. until 8:30 p.m. on May 28, 2016, the loaded fireworks barge will transit from Pier 50 to the launch site near AT&T Park in San Francisco, CA in approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83), where it will remain until the commencement of the fireworks display. Prior to the commencement of the 10-minute fireworks display, at 9:30 p.m. on May 28, 2016, the safety zone will expand to encompass the navigable waters within a radius of 700 feet of approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83). The safety zone shall terminate at 10 p.m.

The effect of the temporary safety zone will be to restrict navigation in the vicinity of the launch site until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep spectators and vessels away from the immediate vicinity of the launch site to ensure the safety of participants, spectators, and transiting vessels.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders (E.O.'s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.'s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

We expect the economic impact of this rule will not rise to the level of necessitating a full Regulatory Evaluation. The safety zone is limited in duration, and is limited to a narrowly tailored geographic area. In addition, although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This rule may affect owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing. This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons. This safety zone would be activated, and thus subject to enforcement, for a limited duration. When the safety zone is activated, vessel traffic could pass safely around the safety zone. The maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone of limited size and duration. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T11–774 to read as follows:

§ 165.T11–774 Safety Zone; San Francisco State Graduation Fireworks Display, San Francisco, CA.

(a) *Location.* This safety zone is established in the navigable waters of the San Francisco Bay near AT&T Park in San Francisco, CA, as depicted in National Oceanic and Atmospheric Administration (NOAA) Chart 18650. During the loading, transit, and arrival of the fireworks barge and until the start of the fireworks display, the temporary safety zone applies to the navigable waters around and under the fireworks barge within a radius of 100 feet. From 1 p.m. until 5 p.m. on May 28, 2016, the fireworks barge will be loading at Pier 50 in San Francisco, CA. The fireworks barge will remain at Pier 50 until the start of the transit. From 8 p.m. until 8:30 p.m. on May 28, 2016, the loaded fireworks barge will transit from Pier 50 to the launch site near AT&T Park in San Francisco, CA in approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83), where it will remain until the commencement of the fireworks display. Prior to the commencement of the 10-minute fireworks display, at 9:30 p.m. on May 28, 2016, the safety zone will expand to encompass the navigable waters within 700 feet of approximate position 37°46′36″ N. 122°22′56″ W. (NAD 83).

(b) *Enforcement period.* The safety zone described in paragraph (a) of this section will be enforced from 1 p.m. to 10 p.m. on May 28, 2016. The Captain of the Port San Francisco (COTP) will notify the maritime community of periods during which this zone will be enforced via Broadcast Notice to Mariners in accordance with § 165.7.

(c) *Definitions.* As used in this section, "designated representative" means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated to assist in the enforcement of the safety zones.

(d) *Regulations.* (1) Under the general regulations in subpart C of this part, entry into, transiting or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or a designated representative. Persons and vessels may request permission to enter the safety zone may contact the Patrol Commander (PATCOM) on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

Dated: April 26, 2016.

Gregory G. Stump,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2016–10892 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–1081]

RIN 1625–AA00

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its safety zones regulation for Annual Events in the Captain of the Port Lake Michigan zone. This amendment updates 18 permanent safety zones and adds 3 new permanent safety zones. These amendments and additions are necessary to protect spectators, participants, and vessels from the hazards associated with annual maritime events, including fireworks displays, boat races, and air shows.

DATES: This rule is effective June 8, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2015–1081 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Joseph McCollum, U.S. Coast Guard Sector Lake Michigan; telephone 414–747–7148, email *Joseph.P.McCollum@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of Proposed Rulemaking
§	Section
U.S.C.	United States Code

II. Background, Information and Regulatory History

On January 20, 2016, the Coast Guard published a Notice of Proposed Rulemaking entitled Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone in the **Federal Register** (81 FR 3069). No comments were received. No public meeting was requested, and none was held.

III. Legal Authority and Need for Rule

The legal basis for this rule is the Coast Guard's authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 160.5; Department of Homeland Security Delegation No. 0170.1.

The purpose of this rulemaking is to update the safety zones in § 165.929 to ensure that they match the times, dates, and dimensions for various marine and triggering events that are expected to be conducted with the Captain of the Port Lake Michigan Zone throughout the year. The purpose of the rulemaking is also to ensure vessels and persons are protected from the specific hazards related to the aforementioned events. These specific hazards include obstructions to the waterway that may cause marine casualties; collisions among vessels maneuvering at a high speed within a channel; the explosive dangers involved in pyrotechnics and hazardous cargo; and flaming/falling debris into the water that may cause injuries.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published on January 20, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule amends 18 permanent safety zones found within table 165.929 in 33 CFR 165.929. These 18 amendments involve updating the location, size, and/or enforcement times for: 11 fireworks displays in various locations; 1 regatta in Spring Lake, Michigan; 3 Air Shows; 1 Facility in Marinette, Wisconsin; 1 boat race from Chicago, Illinois; and 1 ski show in Sister Bay, Wisconsin.

Additionally, this rule adds 3 new safety zones to table 165.929 within § 165.929 for annually-reoccurring events in the Captain of the Port Lake Michigan Zone. These 3 zones were added in order to protect the public from the safety hazards previously described. The 3 additions include 2 safety zones for fireworks displays, and 1 safety zone for a boat parade in Chicago Harbor, Chicago, Illinois. A list of specific changes and additions are available in the attachments within this Docket.

The Captain of the Port Lake Michigan has determined that the safety zones in this rule are necessary to ensure the safety of vessels and people during annual marine or triggering events in the Captain of the Port Lake Michigan zone. Although this rule will be effective year-round, the safety zones in this rule will be enforced only immediately before, during, and after events that pose a hazard to the public and only upon notice by the Captain of the Port Lake Michigan.

The Captain of the Port Lake Michigan will notify the public that the zones in this rule are or will be enforced by all appropriate means to the affected segments of the public, including publication in the **Federal Register**, as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners.

All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port Lake Michigan or his or her designated representative. Entry into, transiting, or anchoring within the safety zones is prohibited unless authorized by the Captain of the Port or his or her designated representative. The Captain of the Port or his or her designated representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of the statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zones created by this rule will be relatively small and effective during the time to ensure safety of spectator and participants for the listed triggering or marine events. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zones, and the rule will allow vessels to seek permission to enter the zones.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V(A), above this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the regional Small Business regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of safety zones for yearly triggering and marine events on and around Lake Michigan. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. An environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES.** We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 165.929 to read as follows:

§ 165.929 Safety Zones; Annual events requiring safety zones in the Captain of the Port Lake Michigan zone.

(a) *Regulations.* The following regulations apply to the safety zones listed in Table 165.929 of this section.

(1) The general regulations in 33 CFR 165.23.

(2) All vessels must obtain permission from the Captain of the Port Lake Michigan or his or her designated representative to enter, move within, or exit a safety zone established in this section when the safety zone is enforced. Vessels and persons granted permission to enter one of the safety zones listed in this section must obey all lawful orders or directions of the Captain of the Port Lake Michigan or his or her designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel must proceed as directed.

(3) The enforcement dates and times for each of the safety zones listed in Table 165.929 are subject to change, but the duration of enforcement would remain the same or nearly the same total number of hours as stated in the table. In the event of a change, the Captain of the Port Lake Michigan will provide notice to the public by publishing a Notice of Enforcement in the **Federal Register**, as well as, issuing a Broadcast Notice to Mariners.

(b) *Definitions.* The following definitions apply to this section:

(1) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port Lake Michigan to monitor a safety zone, permit entry into a safety zone, give legally enforceable orders to persons or vessels within a safety zone, and take other actions authorized by the Captain of the Port Lake Michigan.

(2) *Public vessel* means a vessel that is owned, chartered, or operated by the United States, or by a State or political subdivision thereof.

(3) *Rain date* refers to an alternate date and/or time in which the safety zone would be enforced in the event of inclement weather.

(c) *Suspension of enforcement.* The Captain of the Port Lake Michigan may suspend enforcement of any of these zones earlier than listed in this section. Should the Captain of the Port suspend any of these zones earlier than the listed duration in this section, he or she may make the public aware of this suspension by Broadcast Notice to Mariners and/or on-scene notice by his or her designated representative.

(d) *Exemption.* Public vessels, as defined in paragraph (b) of this section, are exempt from the requirements in this section.

(e) *Waiver.* For any vessel, the Captain of the Port Lake Michigan or his or her designated representative may waive any of the requirements of this section upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of safety or security.

TABLE 165.929

Event	Location [1]	Enforcement date and time [2]
	(a) March Safety Zones	
(1) St. Patrick's Day Fireworks	Manitowoc, WI All waters of the Manitowoc River within the arc of a circle with a 250-foot radius from a center point launch position at 44°05.492′ N., 087°39.332′ W.	The third Saturday of March; 5:30 p.m. to 7 p.m.
(2) Public Fireworks Display	Green Bay, WI All waters of the Fox River in the vicinity of the Main Street and Walnut Street Bridge within an area bounded by the following coordinates; 44°31.211′ N., 088°00.833′ W.; then southwest along the river bank to 44°30.944′ N., 088°01.159′ W.; then southeast to 44°30.890′ N., 088°01.016′ W.; then northeast along the river bank to 44°31.074′ N., 088°00.866′ W.; then northwest returning to the point of origin.	March 15; 11:50 a.m. to 12:30 p.m. Rain date: March 16; 11:50 a.m. to 12:30 p.m.
	(b) April Safety Zones	
(1) Michigan Aerospace Challenge Sport Rocket Launch.	Muskegon, MI All waters of Muskegon Lake, near the West Michigan Dock and Market Corp facility, within the arc of a circle with a 1500-yard radius from the rocket launch site located in position 43°14.018′ N., 086°15.585′ W.	The last Saturday of April; 8 a.m. to 4 p.m.

TABLE 165.929—Continued

Event	Location[1]	Enforcement date and time[2]
(2) Lubbers Cup Regatta	Spring Lake, MI All waters of Spring Lake in Spring Lake, Michigan in the vicinity of Keenan Marina within a rectangle that is approximately 6,300 by 300 feet. The rectangle will be bounded by points beginning at 43°04.914′ N., 086°12.525′ W.; then east to 43°04.958′ N., 086°11.104′ W.; then south to 43°04.913′ N., 086°11.096′ W.; then west to 43°04.867′ N., 086°12.527′ W.; then north back to the point of origin.	April 9; 7:45 a.m. to 6:15 p.m., and April 10; 8:45 a.m. to 1 p.m.
	(c) May Safety Zones	
(1) Tulip Time Festival Fireworks	Holland, MI All waters of Lake Macatawa, near Kollen Park, within the arc of a circle with a 1000-foot radius from the fireworks launch site in approximate center position 42°47.496′ N., 086°07.348′ W.	The first Saturday of May; 9:30 p.m. to 11:30 p.m. Rain date: The first Friday of May; 9:30 p.m. to 11:30 p.m.
(2) Cochrane Cup	Blue Island, IL All waters of the Calumet Saganashkee Channel from the South Halstead Street Bridge at 41°39.442′ N., 087°38.474′ W.; to the Crawford Avenue Bridge at 41°39.078′ N., 087°43.127′ W.; and the Little Calumet River from the Ashland Avenue Bridge at 41°39.098′ N., 087°39.626′ W.; to the junction of the Calumet Saganashkee Channel at 41°39.373′ N., 087°39.026′ W.	The first Saturday of May; 6:30 a.m. to 5 p.m.
(3) Rockets for Schools Rocket Launch.	Sheboygan, WI All waters of Lake Michigan and Sheboygan Harbor, near the Sheboygan South Pier, within the arc of a circle with a 1500-yard radius from the rocket launch site located with its center in position 43°44.914′ N., 087°41.869′ W.	The first Saturday of May; 8 a.m. to 5 p.m.
(4) Celebrate De Pere Fireworks	De Pere, WI All waters of the Fox River, near Voyageur Park, within the arc of a circle with a 500 foot radius from the fireworks launch site located in position 44°27.167′ N., 088°03.833′ W.	The Saturday or Sunday before Memorial Day; 8:30 p.m. to 10 p.m.
	(d) June Safety Zones	
(1) International Bayfest	Green Bay, WI All waters of the Fox River, near the Western Lime Company 1.13 miles above the head of the Fox River, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°31.408′ N., 088°00.710′ W.	The second Friday of June; 9 p.m. to 11 p.m.
(2) Harborfest Music and Family Festival.	Racine, WI All waters of Lake Michigan and Racine Harbor, near the Racine Launch Basin Entrance Light, within the arc of a circle with a 200-foot radius from the fireworks launch site located in position 42°43.722′ N., 087°46.673′ W.	Friday and Saturday of the third complete weekend of June; 9 p.m. to 11 p.m. each day.
(3) Spring Lake Heritage Festival Fireworks.	Spring Lake, MI All waters of the Grand River within the arc of a circle with a 700-foot radius from a barge in center position 43°04.375′ N., 086°12.401′ W.	The third Saturday of June; 9 p.m. to 11 p.m.
(4) Elberta Solstice Festival	Elberta, MI All waters of Betsie Lake within the arc of a circle with a 500-foot radius from the fireworks launch site located in approximate center position 44°37.607′ N., 086°13.977′ W.	The last Saturday of June; 9 p.m. to 11 p.m.
(5) World War II Beach Invasion Re-enactment.	St. Joseph, MI All waters of Lake Michigan in the vicinity of Tiscornia Park in St. Joseph, MI beginning at 42°06.918′ N., 086°29.421′ W.; then west/northwest along the north breakwater to 42°06.980′ N., 086°29.682′ W.; then northwest 100 yards to 42°07.018′ N., 086°29.728′ W.; then northeast 2,243 yards to 42°07.831′ N., 086°28.721′ W.; then southeast to the shoreline at 42°07.646′ N., 086°28.457′ W.; then southwest along the shoreline to the point of origin.	The last Saturday of June; 8 a.m. to 2 p.m.
(6) Ephraim Fireworks	Ephraim, WI All waters of Eagle Harbor and Lake Michigan within the arc of a circle with a 750-foot radius from the fireworks launch site located on a barge in position 45°09.304′ N., 087°10.844′ W.	The third Saturday of June; 9 p.m. to 11 p.m.
(7) Thunder on the Fox	Elgin, IL All waters of the Fox River from the Kimball Street bridge, located at approximate position 42°02.499′ N., 088°17.367′ W., then 1250 yards north to a line crossing the river perpendicularly running through position 42°03.101′ N., 088°17.461′ W.	Friday, Saturday, and Sunday of the third weekend in June; 10 a.m. to 7 p.m. each day.

TABLE 165.929—Continued

Event	Location [1]	Enforcement date and time [2]
(8) Olde Ellison Bay Days Fireworks.	Ellison Bay, WI All waters of Green Bay, in the vicinity of Ellison Bay Wisconsin, within the arc of a circle with a 400-foot radius from the fireworks launch site located on a barge in approximate center position 45°15.595′ N., 087°05.043′ W.	The fourth Saturday of June; 9 p.m. to 10 p.m.
(9) Sheboygan Harborfest Fireworks.	Sheboygan, WI All waters of Lake Michigan and Sheboygan Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°44.914′ N., 087°41.897′ W.	June 15; 8:45 p.m. to 10:45 p.m.
	(e) July Safety Zones	
(1) Town of Porter Fireworks Display.	Porter IN All waters of Lake Michigan within the arc of a circle with a 1000 foot radius from the fireworks launch site located in center position 41°39.927′ N., 087°03.933′ W.	The first Saturday of July; 8:45 p.m. to 9:30 p.m.
(2) City of Menasha 4th of July Fireworks.	Menasha, WI All waters of Lake Winnebago and the Fox River within the arc of a circle with an 800-foot radius from the fireworks launch site located in center position 44°12.017′ N., 088°25.904′ W.	July 4; 9 p.m. to 10:30 p.m.
(3) Pentwater July Third Fireworks	Pentwater, MI All waters of Lake Michigan and the Pentwater Channel within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°46.942′ N., 086°26.625′ W.	July 3; 9 p.m. to 11 p.m. Rain date: July 4; 9 p.m. to 11 p.m.
(4) Taste of Chicago Fireworks	Chicago, IL All waters of Monroe Harbor and Lake Michigan bounded by a line drawn from 41°53.380′ N., 087°35.978′ W.; then southeast to 41°53.247′ N., 087°35.434′ W.; then south to 41°52.809′ N., 087°35.434′ W.; then southwest to 41°52.453′ N., 087°36.611′ W.; then north to 41°53.247′ N., 087°36.573′ W.; then northeast returning to the point of origin.	July 3; 9 p.m. to 11 p.m. Rain date: July 4; 9 p.m. to 11 p.m.
(5) St. Joseph Fourth of July Fireworks.	St. Joseph, MI All waters of Lake Michigan and the St. Joseph River within the arc of a circle with a 1000-foot radius from the fireworks launch site in position 42°06.867′ N., 086° 29.463′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(6) U.S. Bank Fireworks	Milwaukee, WI All waters and adjacent shoreline of Milwaukee Harbor, in the vicinity of Veteran's park, within the arc of a circle with a 1,200-foot radius from the center of the fireworks launch site which is located on a barge in approximate position 43°02.362′ N., 087°53.485′ W.	July 3; 8:30 p.m. to 11 p.m. Rain date: July 4; 8:30 p.m. to 11 p.m.
(7) Manistee Independence Day Fireworks.	Manistee, MI All waters of Lake Michigan, in the vicinity of the First Street Beach, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°14.854′ N., 086°20.757′ W.	July 3; 9 p.m. to 11 p.m. Rain date: July 4; 9 p.m. to 11 p.m.
(8) Frankfort Independence Day Fireworks.	Frankfort, MI All waters of Lake Michigan and Frankfort Harbor, bounded by a line drawn from 44°38.100′ N., 086°14.826′ W.; then south to 44°37.613′ N., 086°14.802′ W.; then west to 44°37.613′ N., 086°15.263′ W.; then north to 44°38.094′ N., 086°15.263′ W.; then east returning to the point of origin.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(9) Freedom Festival Fireworks	Ludington, MI All waters of Lake Michigan and Ludington Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 43°57.171′ N., 086°27.718′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(10) White Lake Independence Day Fireworks.	Montague, MI All waters of White Lake within the arc of a circle with an 800-foot radius from a center position at 43°24.621′ N., 086°21.463′ W.	July 4; 9:30 p.m. to 11:30 p.m. Rain date: July 5; 9:30 p.m. to 11:30 p.m.
(11) Muskegon Summer Celebration July Fourth Fireworks.	Muskegon, MI All waters of Muskegon Lake, in the vicinity of Hartshorn Municipal Marina, within the arc of a circle with a 700-foot radius from a center position at 43°14.039′ N., 086°15.793′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(12) Grand Haven Jaycees Annual Fourth of July Fireworks.	Grand Haven, MI All waters of the Grand River within the arc of a circle with a 800-foot radius from the fireworks launch site located on the west bank of the Grand River in position 43°3.908′ N., 086°14.240′ W.	July 4; 9 p.m. to 11:30 p.m. Rain date: July 5; 9 p.m. to 11:30 p.m.
(13) Celebration Freedom Fireworks.	Holland, MI All waters of Lake Macatawa in the vicinity of Kollen Park within the arc of a circle with a 2000-foot radius of a center launch position at 42°47.440′ N., 086°07.621′ W.	July 4; 10 p.m. to 11:59 p.m. Rain date: July 4; 10 p.m. to 11:59 p.m.

TABLE 165.929—Continued

Event	Location[1]	Enforcement date and time[2]
(14) Van Andel Fireworks Show	Holland, MI All waters of Lake Michigan and the Holland Channel within the arc of a circle with a 1000-foot radius from the fireworks launch site located in approximate position 42°46.351′ N., 086°12.710′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 3; 9 p.m. to 11 p.m.
(15) Saugatuck Independence Day Fireworks.	Saugatuck, MI All waters of Kalamazoo Lake within the arc of a circle with a 500-foot radius from the fireworks launch site in center position 42°39.074′ N., 086°12.285′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(16) South Haven Fourth of July Fireworks.	South Haven, MI All waters of Lake Michigan and the Black River within the arc of a circle with a 1000-foot radius from the fireworks launch site located in center position 42°24.125′ N., 086°17.179′ W.	July 3; 9:30 p.m. to 11:30 p.m.
(17) Town of Dune Acres Independence Day Fireworks.	Dune Acres, IN All Waters of Lake Michigan within the arc of a circle with a 700-foot radius from the fireworks launch site located in position 41°39.303′ N., 087°05.239′ W.	The first Saturday of July; 8:45 p.m. to 10:30 p.m.
(18) Gary Fourth of July Fireworks	Gary, IN All waters of Lake Michigan, approximately 2.5 miles east of Gary Harbor, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 41°37.322′ N., 087°14.509′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(19) Joliet Independence Day Celebration Fireworks.	Joliet, IL All waters of the Des Plains River, at mile 288, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 41°31.522′ N., 088°05.244′ W.	July 3; 9 p.m. to 11 p.m. Rain date: July 4; 9 p.m. to 11 p.m.
(20) Glencoe Fourth of July Celebration Fireworks.	Glencoe, IL All waters of Lake Michigan in the vicinity of Lake Front Park, within the arc of a circle with a 1000-foot radius from a barge in position 42°08.404′ N., 087°44.930′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(21) Lakeshore Country Club Independence Day Fireworks.	Glencoe, IL All waters of Lake Michigan within the arc of a circle with a 600-foot radius from a center point fireworks launch site in approximate position 42°09.130′ N., 087°45.530′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(22) Shore Acres Country Club Independence Day Fireworks.	Lake Bluff, IL All waters of Lake Michigan within the arc of a circle with a 600-foot radius from approximate position 42°17.847′ N., 087°49.837′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(23) Kenosha Independence Day Fireworks.	Kenosha, WI All waters of Lake Michigan and Kenosha Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°35.283′ N., 087°48.450′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(24) Fourthfest of Greater Racine Fireworks.	Racine, WI All waters of Racine Harbor and Lake Michigan within the arc of a circle with a 900-foot radius from a center point position at 42°44.259′ N., 087°46.635′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(25) Sheboygan Fourth of July Celebration Fireworks.	Sheboygan, WI All waters of Lake Michigan and Sheboygan Harbor, in the vicinity of the south pier, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°44.917′ N., 087°41.850′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(26) Manitowoc Independence Day Fireworks.	Manitowoc, WI All waters of Lake Michigan and Manitowoc Harbor, in the vicinity of south breakwater, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 44°05.395′ N., 087°38.751′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(27) Sturgeon Bay Independence Day Fireworks.	Sturgeon Bay, WI All waters of Sturgeon Bay, in the vicinity of Sunset Park, within the arc of a circle with a 1000-foot radius from the fireworks launch site located on a barge in position 44°50.562′ N., 087°23.411′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(28) Fish Creek Independence	Fish Creek, WI All waters of Green Bay, in the vicinity of Fish Creek Harbor, within the arc of a circle with a 1000-foot radius from the fireworks launch site located on a barge in position 45°07.867′ N., 087°14.617′ W.	July 2; 9 p.m. to 11 p.m. Rain date: July 2; 9 p.m. to 11 p.m.
(29) Fire over the Fox Fireworks	Green Bay, WI All waters of the Fox River including the mouth of the East River from the Canadian National Railroad bridge in approximate position 44°31.467′ N., 088°00.633′ W then southwest to the Main St. Bridge in approximate position 44°31.102′ N., 088°00.963′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.

TABLE 165.929—Continued

Event	Location [1]	Enforcement date and time [2]
(30) Celebrate Americafest Ski Show.	Green Bay, WI. All waters of the Fox River, including the mouth of the East River from the West Walnut Street Bridge in approximate position 44°30.912′ N., 088°01.100′ W., then northeast to an imaginary line running perpendicularly across the river through coordinate 44°31.337′ N., 088°00.640′ W.	July 4 from 2:30 p.m. to 4:30 p.m. Rain date: July 5; 2:30 p.m. to 4:30 p.m.
(31) Marinette Fourth of July Celebration Fireworks.	Marinette, WI. All waters of the Menominee River, in the vicinity of Stephenson Island, within the arc of a circle with a 900 foot radius from the fireworks launch site in center position 45°6.232′ N., 087°37.757′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(32) Evanston Fourth of July Fireworks.	Evanston, IL. All waters of Lake Michigan, in the vicinity of Centennial Park Beach, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 42°02.933′ N., 087°40.350′ W.	July 4; 9 p.m. to 11 p.m. Rain date: July 5; 9 p.m. to 11 p.m.
(33) Gary Air and Water Show	Gary, IN. All waters of Lake Michigan bounded by a line drawn from 41°37.217′ N., 087°16.763′ W.; then east along the shoreline to 41°37.413′ N., 087°13.822′ W.; then north to 41°38.017′ N., 087°13.877′ W.; then southwest to 41°37.805′ N., 087°16.767′ W.; then south returning to the point of origin.	July 6 thru 10; 8:30 a.m. to 5 p.m.
(34) Annual Trout Festival Fireworks.	Kewaunee, WI. All waters of Kewaunee Harbor and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 44°27.493′ N., 087°29.750′ W.	Friday of the second complete weekend of July; 9 p.m. to 11 p.m.
(35) Michigan City Summerfest Fireworks.	Michigan City, IN. All waters of Michigan City Harbor and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 41°43.700′ N., 086°54.617′ W.	Sunday of the second complete weekend of July; 8:30 p.m. to 10:30 p.m.
(36) Port Washington Fish Day Fireworks.	Port Washington, WI. All waters of Port Washington Harbor and Lake Michigan, in the vicinity of the WE Energies coal dock, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°23.117′ N., 087°51.900′ W.	The third Saturday of July; 9 p.m. to 11 p.m.
(37) Bay View Lions Club South Shore Frolics Fireworks.	Milwaukee, WI. All waters of Lake Michigan and Milwaukee Harbor, in the vicinity of South Shore Yacht Club, within the arc of a circle with a 900-foot radius from the fireworks launch site in position 42°59.658′ N., 087°52.808′ W.	Friday, Saturday, and Sunday of the second or third weekend of July; 9 p.m. to 11 p.m. each day.
(38) Venetian Festival Fireworks	St. Joseph, MI. All waters of Lake Michigan and the St. Joseph River, near the east end of the south pier, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°06.800′ N., 086°29.250′ W.	Saturday of the third complete weekend of July; 9 p.m. to 11 p.m.
(39) Joliet Waterway Daze Fireworks.	Joliet, IL. All waters of the Des Plaines River, at mile 287.5, within the arc of a circle with a 300-foot radius from the fireworks launch site located in position 41°31.250′ N., 088°05.283′ W.	Friday and Saturday of the third complete weekend of July; 9 p.m. to 11 p.m. each day.
(40) EAA Airventure	Oshkosh, WI. All waters of Lake Winnebago in the vicinity of Willow Harbor within an area bounded by a line connecting the following coordinates: beginning at 43°56.822′ N., 088° 29.904′ W.; then north approximately 5100 feet to 43°57.653′ N., 088° 29.904′ W., then east approximately 2300 feet to 43°57.653′ N., 088° 29.374′ W.; then south to shore at 43°56.933′ N., 088°29.374′ W.; then southwest along the shoreline to 43°56.822′ N,. 088°29.564′ W.; then west returning to the point of origin.	The last complete week of July, beginning Monday and ending Sunday; 8 a.m. to 8 p.m. each day.
(41) Saugatuck Venetian Night Fireworks.	Saugatuck, MI. All waters of Kalamazoo Lake within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in position 42°39.073′ N., 086°12.285′ W.	The last Saturday of July; 9 p.m. to 11 p.m.
(42) Roma Lodge Italian Festival Fireworks.	Racine, WI. All waters of Lake Michigan and Racine Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°44.067′ N., 087°46.333′ W.	Friday and Saturday of the last complete weekend of July; 9 p.m. to 11 p.m.
(43) Chicago Venetian Night Fireworks.	Chicago, IL. All waters of Monroe Harbor and all waters of Lake Michigan bounded by a line drawn from 41°53.050′ N., 087°36.600′ W.; then east to 41°53.050′ N., 087°36.350′ W.; then south to 41°52.450′ N., 087°36.350′ W.; then west to 41°52.450′ N., 087°36.617′ W.; then north returning to the point of origin.	Saturday of the last weekend of July; 9 p.m. to 11 p.m.

TABLE 165.929—Continued

Event	Location[1]	Enforcement date and time[2]
(44) New Buffalo Business Association Fireworks.	New Buffalo, MI All waters of Lake Michigan and New Buffalo Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 41°48.153′ N., 086°44.823′ W.	July 3rd or July 5th; 9:30 p.m. to 11:15 p.m.
(45) Start of the Chicago to Mackinac Race.	Chicago, IL All waters of Lake Michigan in the vicinity of the Navy Pier at Chicago IL, within a rectangle that is approximately 1500 by 900 yards. The rectangle is bounded by the coordinates beginning at 41°53.252′ N., 087°35.430′ W.; then south to 41°52.812′ N., 087°35.430′ W.; then east to 41°52.817′ N., 087°34.433′ W.; then north to 41°53.250′ N., 087°34.433′ W.; then west, back to point of origin.	July 22; 2 p.m. to 4:30 p.m. and July 23; 9 a.m. to 3 p.m.
(46) Fireworks at Pier Wisconsin	Milwaukee, WI All waters of Milwaukee Harbor, including Lakeshore Inlet and the marina at Pier Wisconsin, within the arc of a circle with a 300-foot radius from the fireworks launch site on Pier Wisconsin located in approximate position 43°02.178′ N., 087°53.625′ W.	Dates and times will be issued by Notice of Enforcement and Broadcast Notice to Mariners.
(47) Gills Rock Fireworks	Gills Rock, WI All waters of Green Bay near Gills Rock WI within a 1000-foot radius of the launch vessel in approximate position at 45°17.470′ N., 087°01.728′ W.	July 4; 8:30 p.m. to 10:30 p.m.
(48) City of Menominee 4th of July Celebration Fireworks.	Menominee, MI All Waters of Green Bay, in the vicinity of Menominee Marina, within the arc of a circle with a 900-foot radius from a center position at 45°06.417′ N., 087° 36.024′ W.	July 4; 9 p.m. to 11 p.m.
(49) Miesfeld's Lakeshore Weekend Fireworks.	Sheboygan, WI All waters of Lake Michigan and Sheboygan Harbor within an 800-foot radius from the fireworks launch site located at the south pier in approximate position 43°44.917′ N., 087°41.967′ W.	July 29; 9 p.m. to 10:30 p.m. Rain date: July 30; 9 p.m. to 10:30 p.m.
(50) Marinette Logging and Heritage Festival Fireworks.	Marinette, WI All waters of the Menominee River, in the vicinity of Stephenson Island, within the arc of a circle with a 900-foot radius from the fireworks launch site in position 45°06.232′ N., 087°37.757′ W.	July 13; 9 p.m. to 11 p.m.
(51) Summer in the City Water Ski Show.	Green Bay, WI All waters of the Fox River in Green Bay, WI from the Main Street Bridge in position 44°31.089′ N., 088°00.904′ W then southwest to the Walnut Street Bridge in position 44°30.900′ N., 088°01.091′ W.	Each Wednesday of July through August; 6 p.m. to 6:30 p.m. and 7 p.m. to 7:30 p.m.
(52) Holiday Celebration Fireworks	Kewaunee, WI All waters of Kewaunee Harbor and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 44°27.481′ N., 087°29.735′ W.	July 4; 8:30 p.m. to 10:30 p.m. Rain date: July 5; 8:30 p.m. to 10:30 p.m.
(53) Independence Day Fireworks	Wilmette, IL All waters of Lake Michigan and the North Shore Channel within the arc of a circle with a 1000-foot radius from the fireworks launch site located at approximate center position 42°04.674′ N., 087°40.856′ W.	July 3; 8:30 p.m. to 10:15 p.m.
(54) Neenah Fireworks	Neenah, WI All waters of Lake Winnebago within a 700 foot radius of an approximate launch position at 44° 11.126′ N., 088° 26.941′ W.	July 3 or 4; 8:45 p.m. to 10:30 p.m.
(55) Milwaukee Air and Water Show.	Milwaukee, WI All waters and adjacent shoreline of Lake Michigan in the vicinity of McKinley Park located within an area that is approximately 4800 by 1250 yards. The area will be bounded by the points beginning at 43°02.450′ N., 087°52.850′ W.; then southeast to 43°02.230′ N., 087°52.061′ W.; then northeast to 43°04.543′ N., 087°50.801′ W.; then northwest to 43°04.757′ N., 087°51.512′ W.; then southwest returning to the point of origin.	July 6 thru 10; 8:30 a.m. to 5 p.m.
(f) August Safety Zones		
(1) Super Boat Grand Prix	Michigan City, IN All waters of Lake Michigan bounded by a rectangle drawn from 41°43.655′ N., 086°54.550′ W.; then northeast to 41°44.808′ N., 086°51.293′ W., then northwest to 41°45.195′ N., 086°51.757′ W.; then southwest to 41°44.063′ N., 086°54.873′ W.; then southeast returning to the point of origin.	The first Sunday of August; 9 a.m. to 4 p.m. Rain date: The first Saturday of August; 9 a.m. to 4 p.m.
(2) Port Washington Maritime Heritage Festival Fireworks.	Port Washington, WI All waters of Port Washington Harbor and Lake Michigan, in the vicinity of the WE Energies coal dock, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°23.117′ N., 087°51.900′ W.	Saturday of the last complete weekend of July or the second weekend of August; 9 p.m. to 11 p.m.

TABLE 165.929—Continued

Event	Location [1]	Enforcement date and time [2]
(3) Grand Haven Coast Guard Festival Fireworks.	Grand Haven, MI All waters of the Grand River within the arc of a circle with an 800-foot radius from the fireworks launch site located on the west bank of the Grand River in position 43°03.907′ N., 086°14.247′ W.	First weekend of August; 9 p.m. to 11 p.m.
(4) Sturgeon Bay Yacht Club Evening on the Bay Fireworks.	Sturgeon Bay, WI All waters of Sturgeon Bay within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in approximate position 44°49.297′ N., 087°21.447′ W.	The first Saturday of August; 8:30 p.m. to 10:30 p.m.
(5) Hammond Marina Venetian Night Fireworks.	Hammond, IN All waters of Hammond Marina and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 41°41.883′ N., 087°30.717′ W.	The first Saturday of August; 9 p.m. to 11 p.m.
(6) North Point Marina Venetian Festival Fireworks.	Winthrop Harbor, IL All waters of Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°28.917′ N., 087°47.933′ W.	The second Saturday of August; 9 p.m. to 11 p.m.
(7) Waterfront Festival Fireworks	Menominee, MI All Waters of Green Bay, in the vicinity of Menominee Marina, within the arc of a circle with a 1000-foot radius from a center position at 45°06.447′ N., 087°35.991′ W.	August 3; 9 p.m. to 11 p.m.
(8) Ottawa Riverfest Fireworks	Ottawa, IL All waters of the Illinois River, at mile 239.7, within the arc of a circle with a 300-foot radius from the fireworks launch site located in position 41°20.483′ N., 088°51.333′ W.	The first Sunday of August; 9 p.m. to 11 p.m.
(9) Chicago Air and Water Show	Chicago, IL All waters and adjacent shoreline of Lake Michigan and Chicago Harbor bounded by a line drawn from 41°55.900′ N at the shoreline, then east to 41°55.900′ N., 087°37.200′ W., then southeast to 41°54.000′ N, 087°36.000′ W., then southwestward to the northeast corner of the Jardine Water Filtration Plant, then due west to the shore.	August 18 thru 21; 8:30 a.m. to 5 p.m.
(10) Pentwater Homecoming Fireworks.	Pentwater, MI All waters of Lake Michigan and the Pentwater Channel within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°46.942′ N., 086°26.633′ W.	Saturday following the second Thursday of August; 9 p.m. to 11 p.m.
(11) Chicago Match Cup Race	Chicago, IL All waters of Chicago Harbor in the vicinity of Navy Pier and the Chicago Harbor break wall bounded by coordinates beginning at 41°53.617′ N., 087°35.433′ W.; then south to 41°53.400′ N., 087°35.433′ W.; then west to 41°53.400′ N., 087°35.917′ W.; then north to 41°53.617′ N., 087°35.917′ W.; then back to point of origin.	August 6 thru 11; 8 a.m. to 8 p.m.
(12) New Buffalo Ship and Shore Fireworks.	New Buffalo, MI All waters of Lake Michigan and New Buffalo Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 41°48.150′ N., 086°44.817′ W.	August 10; 9:30 p.m. to 11:15 p.m.
(13) Operations at Marinette Marine	Marinette, WI All waters of the Menominee River in the vicinity of Marinette Marine Corporation, from the Bridge Street Bridge located in position 45°06.188′ N., 087°37.583′ W., then approximately .95 NM south east to a line crossing the river perpendicularly passing through positions 45°05.881′ N., 087°36.281′ W. and 45°05.725′ N., 087°36.385′ W.	This zone will be enforced in the case of hazardous cargo operations or vessel launch by issue of Notice of Enforcement and Marine Broadcast.
(14) Fireworks Display	Winnetka, IL All waters of Lake Michigan within the arc of a circle with a 900-foot radius from a center point barge located in approximate position 42°06.402′ N., 087°43.115′ W.	Third Saturday of August; 9:15 p.m. to 10:30 p.m.
(15) Algoma Shanty Days Fireworks.	Algoma, WI All waters of Lake Michigan and Algoma Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in a center position of 44°36.400′ N., 087°25.900′ W.	Sunday of the second complete weekend of August; 9 p.m. to 11 p.m.
(16) Venetian Night Parade	Chicago, IL All waters of Lake Michigan, in the vicinity of Navy Pier, bounded by coordinates beginning at 41° 53.771′ N., 087°35.815′ W.; and then south to 41°53.367′ N., 087°35.814′ W.; then west to 41°53.363′ N., 087°36.587′ W.; then north to 41°53.770′ N., 087°36.601′ W.; then east back to the point of origin.	Last Saturday of August; 6:30 p.m. to 9:30 p.m.

TABLE 165.929—Continued

Event	Location[1]	Enforcement date and time[2]
(g) September Safety Zones		
(1) ISAF Nations Cup Grand Final Fireworks Display.	Sheboygan, WI All waters of Lake Michigan and Sheboygan Harbor, in the vicinity of the south pier in Sheboygan Wisconsin, within a 500 foot radius from the fireworks launch site located on land in position 43°44.917′ N., 087°41.850′ W.	September 13; 7:45 p.m. to 8:45 p.m.
(2) Sister Bay Marinafest Ski Show	Sister Bay, WI All waters of Sister Bay within an 800-foot radius of position 45°11.585′ N., 087°07.392′ W.	September 3; 1 p.m. to 3:15 p.m.
(3) Sister Bay Marinafest Fireworks	Sister Bay, WI All waters of Sister Bay within an 800-foot radius of the launch vessel in approximate position 45°11.585′ N., 087°07.392′ W.	September 3 and 4; 8:15 p.m. to 10 p.m.
(h) October Safety Zones		
(1) Corn Festival Fireworks	Morris, IL All waters of the Illinois River within a 560 foot radius from approximate launch position at 41°21.173′ N., 088°25.101′ W.	The first Saturday of October; 8:15 p.m. to 9:15 p.m.
(i) November Safety Zones		
(1) Downtown Milwaukee Fireworks	Milwaukee, WI All waters of the Milwaukee River in the vicinity of the State Street Bridge within the arc of a circle with a 300-foot radius from a center point fireworks launch site in approximate position 43°02.559′ N., 087°54.749′ W.	The third Thursday of November; 6 p.m. to 8 p.m.
(2) Magnificent Mile Fireworks Display.	Chicago, IL All waters and adjacent shoreline of the Chicago River bounded by the arc of the circle with a 210-foot radius from the fireworks launch site with its center in approximate position of 41°53.350′ N., 087°37.400′ W.	The third weekend in November; sunset to termination of display.
(j) December Safety Zones		
(1) New Years Eve Fireworks	Chicago, IL All waters of Monroe Harbor and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located on a barge in approximate position 41°52.683′ N., 087°36.617′ W.	December 31; 11 p.m. to January 1 at 1 a.m.

[1] All coordinates listed in Table 165.929 reference Datum NAD 1983.

[2] As noted in paragraph (a)(3) of this section, the enforcement dates and times for each of the listed safety zones are subject to change.

Dated: April 21, 2016.

A.B. Cocanour,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. 2016–10306 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 674

[FTA Docket No. FTA–2015–0003]

RIN 2132–AB19

State Safety Oversight; Corrections

AGENCY: Federal Transit Administration, DOT.

ACTION: Final rule; corrections.

SUMMARY: The Federal Transit Administration (FTA) is correcting a final rule that appeared in the **Federal Register** on March 16, 2016 (80 FR 14230). The document contained incorrect estimated total annual burden on respondents. This document corrects the estimated total annual burden hours for State Safety Oversight (SSO) Agencies and Rail Transit Agencies (RTA).

DATES: Effective on May 9, 2016.

FOR FURTHER INFORMATION CONTACT: For program matters, Brian Alberts, Program Analyst, FTA Office of Transit Safety and Oversight, telephone 202–366–1783 or *Brian.Alberts@dot.gov.* For legal matters, Richard Wong, FTA Office of Chief Counsel, telephone 202–366–4011 or *Richard.Wong@dot.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2016–05489 published in the **Federal Register** of Wednesday, March 16, 2016 (80 FR 14230), the following corrections are made:

1. On page 14255, in the second column, the third full paragraph that starts with "*Respondents:*" is corrected to read as follows:

Total Respondents: 90 (30 States + 60 Rail Transit Agencies).

2. On page 14255, in the second column, the fifth full paragraph that starts with "*Estimated Total Annual Burden Hours:*" is corrected to read as follows:

Total Annual Burden Hours: 586,443 hours (336,843 State Safety Oversight (SSO) Agency hours + 249,600 Rail Transit Agency (RTA) hours).

FTA estimates that the annual information collection burden for States implementing 49 CFR part 674 requirements is 336,843 total hours. This equates to approximately 11,228 hours devoted to information collection activities for each of the estimated 30 States in the SSO Program. FTA estimates that the annual information collection burden for RTAs is approximately 249,600 total hours, or approximately 4,160 hours for each of the 60 rail transit agencies in the SSO Program.

William Hyre,

Deputy Associate Administrator for Administration.

[FR Doc. 2016–10836 Filed 5–6–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE611

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the B season apportionment of the 2016 Pacific cod total allowable catch allocated to trawl catcher vessels in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), May 4, 2016, through 1200 hours, A.l.t., June 10, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season apportionment of the 2016 Pacific cod total allowable catch (TAC) allocated to trawl catcher vessels in the BSAI is 5,460 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the B season apportionment of the 2016 Pacific cod TAC allocated to trawl catcher vessels in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 5,000 mt and is setting aside the remaining 460 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by catcher vessels using trawl gear in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of May 3, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 4, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–10832 Filed 5–4–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 89
Monday, May 9, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6418; Directorate Identifier 2015–NM–158–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A330–200 Freighter, –200, and –300 series airplanes; and Airbus Model A340–200, –300, –500, and –600 series airplanes. This proposed AD was prompted by reports of fuel leaking through fuel pump electrical connectors and fuel pump electrical connector damage caused by the build-up of moisture behind the electrical connector. Electrical connectors that become damaged by moisture can create an ignition source and a fuel leak. This proposed AD would require an inspection of the fuel pumps to identify their part numbers and replacement of affected pumps. We are proposing this AD to prevent a potential ignition source and a fuel leak due to damaged fuel pump electrical connectors. This condition creates a flammability risk in an area adjacent to the fuel tank.

DATES: We must receive comments on this proposed AD by June 23, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com;* Internet: *http://www.airbus.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6418; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1138; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6418; Directorate Identifier 2015–NM–158–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2015–0194, dated September 22, 2015, to correct an unsafe condition for all Airbus Model A330–200 Freighter, –200, and –300 series airplanes; and Airbus Model A340–200, –300, –500, and –600 series airplanes. The MCAI states:

> Operators reported cases of fuel leak through fuel pump electrical connectors. Subsequent investigation revealed fuel pump electrical connector damage caused by moisture build up behind the electrical connector.
>
> This condition, if not detected and corrected, could create concurrently an ignition source and fuel leak as a result of a single failure, resulting in exposure to a flammability risk in an adjacent area to the fuel tank.
>
> To address this unsafe condition, Airbus published Service Bulletins (SB) A330–28–3127, SB A340–28–4138 and SB A340–28–5060, providing inspection/identification instructions, and instructions for replacement of the fuel pumps.
>
> For the reasons described above, this [EASA] AD requires identification and replacement of the affected fuel pumps.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6418.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information:

- Airbus Service Bulletin A330–28–3127, Revision 01, dated September 24, 2015.
- Airbus Service Bulletin A340–28–4138, Revision 01, dated September 24, 2015.
- Airbus Service Bulletin A340–28–5060, Revision 01, dated September 24, 2015.

The service information describes procedures to identify and replace affected fuel pumps with serviceable fuel pumps. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 99 airplanes of U.S. registry.

We also estimate that it will take about 4 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $33,660, or $340 per product.

In addition, we estimate that any necessary follow-on actions would take about 17 work-hours and require parts costing $10,400, for a cost of $11,845 per product. We have no way of determining the number of aircraft that might need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2016–6418; Directorate Identifier 2015–NM–158–AD.

(a) Comments Due Date

We must receive comments by June 23, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A330–223F and –243F airplanes; A330–201, –202, –203, –223, and –243 airplanes; A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; and Airbus Model A340–211, –212, and –213 airplanes; A340–311, –312, and –313 airplanes; A340–541 airplanes; and A340–642 airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by reports of fuel leaking through fuel pump electrical connectors and fuel pump electrical connector damage caused by the build-up of moisture behind the electrical connector. Electrical connectors that become damaged by moisture can create an ignition source and a fuel leak. We are issuing this AD to prevent a potential ignition source and a fuel leak due to damaged fuel pump electrical connectors. This condition creates a flammability risk in an area adjacent to the fuel tank.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Identify Part Numbers

Within 48 months after the effective date of this AD, inspect each fuel pump to identify the part number (P/N) in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–28–3127, Revision 01, dated September 24, 2015; Airbus Service Bulletin A340–28–4138, Revision 01, dated September 24, 2015; or Airbus Service Bulletin A340–28–5060, Revision 01, dated September 24, 2015; as applicable to airplane type. A review of airplane delivery or maintenance records is acceptable in lieu of this inspection if the part number of the fuel pump can be conclusively determined from that review.

(h) Modification

If, during the inspection required by paragraph (g) of this AD, it is determined that an affected fuel pump is installed: Within the compliance time specified in paragraph (h)(1) or (h)(2) of this AD, depending on the configuration of the affected fuel pumps installed, replace each affected fuel pump with a serviceable fuel pump in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–28–3127, Revision 01, dated September 24, 2015; Airbus Service Bulletin A340–28–4138, Revision 01, dated September 24, 2015; or Airbus Service Bulletin A340–28–5060, Revision 01, dated September 24, 2015; as applicable to airplane type.

(1) For affected fuel pumps that have a part number or combination of part numbers that are specified in paragraphs (h)(1)(i) through (h)(1)(vi) of this AD: Do the replacement within 72 months after the effective date of this AD.

(i) All of the affected fuel pumps have P/N 568–1–28300–001.

(ii) All of the affected fuel pumps have P/N 568–1–28300–002.

(iii) The affected fuel pumps have a combination of P/Ns 568–1–28300–001 and 568–1–28300–002.

(iv) The affected fuel pumps have a combination of P/Ns 568–1–28300–001 and 568–1–28300–101.

(v) The affected fuel pumps have a combination of P/Ns 568–1–28300–002 and 568–1–28300–101.

(vi) The affected fuel pumps have a combination of P/Ns 568–1–28300–001, 568–1–28300–002, and 568–1–28300–101.

(2) For affected fuel pumps that have a part number or combination of part numbers that are specified in paragraphs (h)(2)(i) through (h)(2)(iii) of this AD: Do the replacement within 96 months after the effective date of this AD.

(i) All of the affected fuel pumps have P/N 568–1–28300–100.

(ii) All of the affected fuel pumps have P/N 568–1–28300–101.

(iii) The affected fuel pumps have a combination of P/Ns 568–1–28300–100 and 568–1–28300–101.

(i) Definitions

(1) For the purpose of this AD, an "affected fuel pump" is defined as any pump having P/N 568–1–28300–001, 568–1–28300–002, 568–1–28300–100, or 568–1–28300–101.

(2) For the purpose of this AD, a "serviceable fuel pump" is a pump having a part number not listed in paragraph (i)(1) of this AD.

(j) No Reporting Requirement

Although Airbus Service Bulletin A330–28–3127, Revision 01, dated September 24, 2015; Airbus Service Bulletin A340–28–4138, Revision 01, dated September 24, 2015; or Airbus Service Bulletin A340–28–5060, Revision 01, dated September 24, 2015, specifies to submit certain information to the manufacturer, and specifies that action as "RC" (Required for Compliance), this AD does not include that requirement.

(k) Parts Installation Prohibition

After the identification of the fuel pump part numbers as required by paragraph (g) of this AD, comply with the prohibition required by paragraph (k)(1) or (k)(2) of this AD, as applicable.

(1) For an airplane that does not have an affected fuel pump installed: After the identification of the fuel pump part numbers as required by paragraph (g) of this AD, do not install an affected fuel pump.

(2) For an airplane that has an affected fuel pump installed: After modification of an airplane as required by paragraph (h) of this AD, no person may install an affected fuel pump on any airplane.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using service information included in paragraphs (l)(1), (l)(2), and (l)(3) of this AD, which are not incorporated by reference in this AD.

(1) Airbus Service Bulletin A330–28–3127 dated July 14, 2015.

(2) Airbus Service Bulletin A340–28–4138 dated July 14, 2015.

(3) Airbus Service Bulletin A340–28–5060 dated July 14, 2015.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1138; fax: 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as provide by paragraph (j) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(n) Related Information

(1) Refer to Continuing Airworthiness Information (MCAI) EASA AD 2015–0194, dated September 22, 2015, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6418.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com;* Internet: *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 28, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10633 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 111

[Docket No. FDA–2015–N–0797]

The Food and Drug Administration Food Safety Modernization Act: Focus on Strategic Implementation of Prevention-Oriented Import Safety Programs; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing three one-day public meetings in different regions throughout the United States to provide importers and other interested persons an opportunity to have an in-depth discussion on the implementation of the FDA Food Safety Modernization Act (FSMA) import safety programs (*i.e.,* foreign supplier verification programs (FSVPs) for importers of food for humans and animals, accreditation of third-party certification bodies, and FDA's Voluntary Qualified Importer Program (VQIP)). During these meetings, participants and key FDA subject matter experts will discuss the next phase of FSMA implementation related to import safety programs, which includes establishing the operational framework for these programs and plans for guidance documents, training, education, and technical assistance. The purpose of the regional outreach public meetings is to continue the dialogue with the importer community on FSMA and elicit ideas that will help to inform FDA and our stakeholders on how to continue to work together to successfully comply with FSMA mandates and regulations.

DATES: See section III for dates and times of the regional outreach meetings, closing dates for advance registration, and requests for special accommodations due to disability.

ADDRESSES: See section III for meeting locations.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting, or to register by phone: Peggy Walker, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 214–384–0667, FAX: 469–854–6992, email: *pwalker@planningprofessionals.com.*

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1731, email: *Juanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 2, 2014, we released our "Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)," electronically at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm*, to guide the next phase of FSMA implementation following the establishment of regulations and relevant programs. Within the "Operational Strategy for Implementing FSMA," there is an appendix that outlines guiding principles for how the operational strategy can be implemented with respect to food and feed facilities, produce safety standards, and import oversight. The guiding principles include the following: Expanding inspection and surveillance; administering new administrative enforcement tools; developing guidance, education, and technical assistance tools; and building a prevention-oriented import system.

On April 23, 2015, FDA hosted a public meeting as an opportunity for interested persons to share views concerning how FDA should address the operational aspects of FSMA implementation as suggested by the guiding principles. We provided an update on current planning efforts and received input from the public to inform the development of operational work plans in the areas of produce safety, preventive controls for foods for humans and animals, measures to address intentional adulteration, FSVP, and the FDA third-party accreditation program. In addition, we established a docket to obtain comments on a range of operational issues that we might consider in our FSMA implementation approach.

On March 21, 2016, FDA hosted a kick-off public meeting to brief participants on the key components of the FSVP and third-party certification final rules; brief participants on the status of the VQIP; discuss the plans for guidance documents related to import safety, as well as training, education, and technical assistance; provide an update on the development of a risk-based industry oversight framework that is at the core of FSMA; and answer questions about these import programs. The public meeting was an opportunity for FDA to share its current thinking on implementation plans for programs related to import safety. During that public meeting, we mentioned plans to continue dialogue on implementation of these import safety programs with a series of regional meeting across the United States.

The agendas, recordings, and transcripts for the FSMA implementation and prevention-oriented import system public meetings are accessible on our FSMA Web site at *http://www.fda.gov/FSMA.*

II. Purpose and Format of the Regional Outreach Meetings

FDA plans to hold three one-day public meetings in different regions throughout the United States to provide importers and other interested persons an opportunity to have an in-depth discussion on the implementation of FSMA import safety programs (*i.e.*, FSVPs for importers of food for humans and animals, accreditation of third-party certification bodies, and FDA's VQIP). We invite the public to provide information, share experiences, and raise issues on implementation topics related to import safety including (but not limited to): Increasing awareness/reaching the regulated community, potential partners on outreach and implementation, state of readiness, barriers to implementation, training and education for industry and regulators, guidance needs, promotion of best practices, technical assistance, compliance and enforcement issues, and long-term implementation success. The purpose of the regional outreach meetings is to continue the dialogue with the importer community and elicit ideas that will help to inform FDA and the regulated population on how to continue to work together to successfully comply with FSMA mandates and regulations.

III. How To Participate in the Public Meeting

We are holding three one-day public meetings in different regions throughout the United States.

Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the regional outreach meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is very limited.

Table 1 provides information on participation in the regional outreach meetings.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

Regional outreach meetings	Date	Address	Preregister	Electronic address	Special accommodations	Other information
California Regional Outreach Meeting.	June 7, 2016, from 8:30 a.m. to 3 p.m. PDT.	The Hilton Costa Mesa, 3050 Bristol Street, Costa Mesa, CA 92626.	May 26, 2016: Closing date for Registration.	Please preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	May 25, 2016: Closing date to request special accommodations due to a disability.	Registration check-in begins at 8 a.m.
New Jersey Regional Outreach Meeting.	June 15, 2016, from 8:30 a.m. to 3 p.m. EDT.	Renaissance Meadowlands Hotel, 801 Rutherford Avenue, Rutherford, NJ 07070.	June 3, 2016: Closing date for Registration.	Please preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	June 2, 2016: Closing date to request special accommodations due to a disability.	Registration check-in begins at 8 a.m.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING—Continued

Regional outreach meetings	Date	Address	Preregister	Electronic address	Special accommodations	Other information
Michigan Regional Outreach Meeting.	June 21, 2016, from 8:30 a.m. to 3 p.m. EDT.	Double Tree Suites by Hilton Hotel Detroit—Downtown Fort Shelby, 525 W Lafayette Blvd., Detroit, MI 48226.	June 10, 2016: Closing date for Registration.	Please preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	June 9, 2016: Closing date to request special accommodations due to a disability.	Registration check-in begins at 8 a.m.

[1] You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Peggy Walker, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 214–384–0667, FAX: 469–854–6992, email: *pwalker@planningprofessionals.com.*

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10799 Filed 5–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 1000, 1003, 1005, 1006, and 1007

[Docket No. FR 5861–P–01]

RIN 2577–AC96

Equal Access to Housing in HUD's Native American and Native Hawaiian Programs—Regardless of Sexual Orientation or Gender Identity

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise regulations for HUD's Native American and Native Hawaiian programs to incorporate existing rules that require HUD programs to be open to all eligible individuals and families regardless of sexual orientation, gender identity, or marital status. Since HUD promulgated the "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" final rule in February, 2012, HUD has required that HUD-assisted and HUD-insured housing be made available in accordance with program eligibility requirements and without regard to sexual orientation, gender identity, or marital status, and has generally prohibited inquiries into sexual orientation or gender identity. In applying these non-discrimination requirements to HUD's Native American and Native Hawaiian programs, this proposed rule would further the Federal goal of providing decent housing and a suitable living environment for all.

DATES: *Comments due:* July 8, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m., weekdays, at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service, toll free, at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: [Contact Name to be Inserted], Office of Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 5206, Washington, DC 20410–8000; telephone number 202–708–2333 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On February 3, 2012, HUD published in the **Federal Register**, at 77 FR 5662, a final rule titled "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" (the Equal Access Rule) in order to address evidence that lesbian, gay, bisexual, and transgender (LGBT) individuals and families do not have equal access to housing, and to promote the federal goal of providing decent housing and a suitable living environment for all.[1] The Equal Access Rule requires that housing assisted or insured by HUD be made available to individuals and families without regard to actual or perceived sexual orientation, gender identity, or marital status. Additionally, the rule prohibits owners and administrators of HUD-assisted or HUD-insured housing, approved lenders in an FHA mortgage insurance program, and any other recipients or subrecipients of HUD funds from inquiring about sexual orientation or gender identity to determine eligibility for HUD-assisted or HUD-insured housing. The prohibition on inquiries regarding sexual orientation or gender identity does not prohibit individuals from voluntarily self-identifying sexual orientation or gender identity, and it provides a limited exception for lawful inquiries of an applicant's or occupant's sex where the housing provided or to be provided is temporary, emergency shelter with shared sleeping areas or bathrooms, or to determine the number of bedrooms to which a household may be entitled These protections are now codified at 24 CFR 5.105(a)(2). The Equal Access Rule also provides definitions for the terms sexual orientation and gender identity, and revises the definition for the term family at § 5.403, which applies broadly unless otherwise provided in the regulations for a specific HUD program. In addition, the Equal Access Rule made revisions to specific HUD programs. See 24 CFR part 200—Introduction to FHA Programs, revisions to sections defining family, determining income adequacy, and applying the definition of family; 24 CFR part 570—Community Development Block Grants, revisions to the section defining family and household; 24 CFR part 574—Housing Opportunities for Persons with AIDS, revision to the section defining family; 24 CFR part 891—Supportive Housing For the Elderly and Persons with Disabilities, revision to the definition of family; and 24 CFR part 892—Section 8 Tenant-Based Assistance: Housing Choice Voucher Program, revisions to the sections defining family, eligibility, and targeting.

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[1] See Section 2 of the Housing Act of 1949 at 42 U.S.C. 1441 (Congressional Declaration of National Housing Policy).

In publishing the Equal Access Rule, HUD noted that establishment of the equal access policy in HUD's Native American programs would be undertaken by separate rulemaking. (See 77 FR 5662, at footnote 3.) Since implementing the Equal Access Rule, it has been HUD's intention to apply the same non-discrimination requirements to HUD's Native American and Native Hawaiian programs, after undergoing tribal consultation to solicit feedback on this proposal.

Since the publication of the Equal Access Rule, the Federal Government has continued to broaden protections for LGBT individuals and families where Federal funding is involved. For example, the Violence Against Women Reauthorization Act of 2013 (VAWA) includes a provision that prohibits discrimination based on gender identity and sexual orientation by recipients of VAWA funds or assistance administered by the U.S. Department of Justice's Office on Violence Against Women. Additionally, on July 21, 2014, President Obama signed Executive Order 13672, titled, "Further Amendments to Executive Order 11478, Equal Employment Opportunity in the Federal Government, and Executive Order 11246, Equal Employment Opportunity," which prohibits the Federal Government and Federal contractors from discriminating on the basis of sexual orientation or gender identity.[2]

As discussed in the preamble to the January 24, 2011, proposed Equal Access Rule, at 76 FR 4194, and in the preamble to the final Equal Access Rule, the Federal government has a goal of providing everyone in the United States with a decent and suitable place to live. In furtherance of this, HUD has a responsibility to ensure that all who are otherwise eligible to participate in HUD programs will not be excluded based on sexual orientation, gender identity, or marital status, which are irrelevant to eligibility for or participation in those programs. By applying the core protections of the Equal Access Rule to HUD's Native American and Native Hawaiian programs, HUD will conform with its own precedent of equal access, as well as other Federal precedent, to ensure that Federal funds are not used to exclude persons from Federally-assisted programs because of sexual orientation, gender identity, or marital status. Applying the Equal Access Rule to HUD's Native American and Native Hawaiian programs will also ensure consistency where there is an overlap between HUD's Native American and Native Hawaiian programs and other HUD programs, which are already subject to the requirements in the Equal Access Rule.

II. This Proposed Rule

With tribal consultation completed, as explained below in Section III, HUD is proposing to amend regulations for its Native American and Native Hawaiian programs so that they conform to the Equal Access Rule. The regulations would require that access be provided without regard to actual or perceived sexual orientation, gender identity, or marital status in housing assisted or insured under these programs. The proposed rule would add the equal access to HUD-assisted or insured housing requirements in 24 CFR 5.105(a)(2) to the Native American and Native Hawaiian programs identified below. HUD's rule at 24 CFR 5.105(a)(2) incorporates the definitions of "sexual orientation" and "gender identity" provided in § 5.100, and these definitions will apply to the Native American and Native Hawaiian programs. This proposed rule would not change the definition of "family" for Native American and Native Hawaiian programs. At the final rule stage, HUD intends to make conforming amendments to § 5.105(a)(2) to make explicit that the requirements in § 5.105(a)(2) apply to housing with loans guaranteed or insured under one of HUD's Native American or Native Hawaiian housing programs and not only the FHA mortgage insurance program.

Specifically, this proposed rule would amend HUD's regulations for Native American Housing Activities, at 24 CFR part 1000; Community Development Block Grants for Indian Tribes and Alaska Native Villages, at 24 CFR part 1003; the Section 184 Indian Home Loan Guarantee Program, at 24 CFR part 1005; the Native Hawaiian Housing Block Grant Program, at 24 CFR part 1006; and Section 184A Loan Guarantees For Native Hawaiian Housing, at 24 CFR part 1007 to incorporate the § 5.105(a)(2) requirements.

On November 20, 2015, HUD published in the **Federal Register**, at 80 FR 72642, a proposed rule titled "Equal Access in Accordance with an Individual's Gender Identity in Community Planning and Development Programs" (the CPD Equal Access Rule), which would amend certain provisions of § 5.105(a)(2). While the CPD Equal Access Rule would not amend the Equal Access Rule's requirement that access be provided without regard to actual or perceived sexual orientation, gender identity, or marital status in HUD-assisted or HUD-insured housing, the CPD Equal Access Rule is proposing changes to 24 CFR 5.105(a)(2) and to the definition of "gender identity" in 24 CFR 5.100, which this rule is seeking to adopt for Native American and Native Hawaiian programs. If the CPD Equal Access Rule and this rule both become final, the changes proposed in the CPD Equal Access Rule would apply to the Native American and Native Hawaiian programs.

Specifically, the proposed rule seeks to remove the prohibition of inquiries at § 5.105(a)(2)(ii), which HUD believes may hinder a provider from making an appropriate placement decision with regard to transgender individuals and other persons who do not identify with the sex they were assigned at birth. For this reason, the CPD Equal Access Rule proposes to remove the prohibition of inquiries. It is not HUD's intent, however, to now permit recipients or subrecipients to ask questions in order to seek information that could be used for discriminatory purposes. The CPD Equal Access Rule is also proposing to amend the definition of gender identity in § 5.100, which currently provides that "Gender identity means actual or perceived gender-related characteristics." The new definition would more clearly reflect the difference between actual and perceived gender identity. The definition of gender identity would now read as follows: "Gender identity means the gender with which a person identifies, regardless of the sex assigned to that person at birth. Perceived gender identity means the gender with which a person is perceived to identify based on that person's appearance, behavior, expression, other gender-related characteristics, or sex assigned to the individual at birth."

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[2] See *http://www.gpo.gov/fdsys/pkg/FR-2014-07-23/pdf/2014-17522.pdf.*

III. Tribal Consultation

HUD's policy is to consult with Indian tribes early in the rulemaking process on matters that have tribal implications. Accordingly, on January 28, 2015, HUD sent letters to Tribal leaders informing them of the nature of the forthcoming rule and soliciting comments. The deadline for comments under this informal consultation was February 27, 2015. HUD received one response to the consultation letter from a tribally designated housing entity, which said it opposed the proposed rule.

HUD received a second response on behalf of a housing development and management organization that states that section 106(b)(2)(A) of the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) (25 U.S.C. 4166(b)(2)(A)) requires HUD to use negotiated rulemaking in order to amend NAHASDA regulations.. The letter also stated that the rule should not prohibit tribes from considering marital status in making eligibility determinations for housing assisted or insured by HUD because tribes have authority to govern domestic relations of their members. This letter also asked for more specificity on the rule and more ways to participate in the consultation process. The requirement to undertake negotiated rulemaking pertains to regulations that implement NAHASDA statutory requirements. This rule pertains to nondiscrimination requirements and does not pertain to regulations that implement NAHASDA statutory requirements.

The entities that submitted comments in response to the consultation letter, and all other tribes and interested parties now have the opportunity to provide further comments on this proposed rule, and HUD welcomes such comments.

IV. Findings and Certifications

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This proposed rule does not impose any new costs, or modify existing costs, applicable to HUD grantees. Rather, the purpose of this proposed rule is to ensure equal access to HUD's Native American and Native Hawaiian programs, regardless of sexual orientation or gender identity. Accordingly, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Environmental Impact

This proposed rule sets forth nondiscrimination standards. Accordingly, under 24 CFR 50.19(c)(3), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either: (i) Imposes substantial direct compliance costs on state and local governments and is not required by statute, or (ii) preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This proposed rule would not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects

24 CFR Part 1000

Aged, Community development block grants, Grant programs—housing and community development, Grant programs—Indians, Indians, Individuals with disabilities, Public housing, Reporting and recordkeeping requirements.

24 CFR Part 1003

Alaska, Community development block grants, Grant programs—housing and community development, Grant programs—Indians, Indians, Reporting and recordkeeping requirements.

24 CFR Part 1005

Indians, Loan programs—Indians, Reporting and recordkeeping requirements.

24 CFR Part 1006

Community development block grants, Grant programs—housing and community development, Grant programs—Indians, Hawaiian Natives, Low and moderate income housing, Reporting and recordkeeping requirements.

24 CFR Part 1007

Hawaiian Natives, Loan programs—housing and community development, Loan programs—Indians, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, HUD proposes to amend 24 CFR parts 1000, 1003, 1005, 1006, and 1007, as follows:

PART 1000—NATIVE AMERICAN HOUSING ACTIVITIES

■ 1. The authority citation for 24 CFR part 1000 continues to read as follows:

Authority: 25 U.S.C. 4101 *et seq.*; 42 U.S.C. 3535(d).

■ 2. In § 1000.12, add paragraph (e) to read as follows:

§ 1000.12 What nondiscrimination requirements are applicable?

* * * * *

(e) The equal access to HUD-assisted or insured housing requirements in 24 CFR 5.105(a)(2).

PART 1003—COMMUNITY DEVELOPMENT BLOCK GRANTS FOR INDIAN TRIBES AND ALASKA NATIVE VILLAGES

■ 3. The authority citation for 24 CFR part 1003 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 5301 *et seq.*

■ 4. In § 1003.601, add paragraph (c) to read as follows:

§ 1003.601 Nondiscrimination.

* * * * *

(c) A grantee shall comply with the equal access to HUD-assisted or insured housing requirements in 24 CFR 5.105(a)(2).

PART 1005—LOAN GUARANTEES FOR INDIAN HOUSING

■ 5. The authority citation for 24 CFR part 1005 continues to read as follows:

Authority: 12 U.S.C. 1715z–13a; 15 U.S.C. 1639c; 42 U.S.C. 3535(d).

■ 6. Add § 1005.115 to read as follows:

§ 1005.115 Equal Access.

The equal access to HUD-assisted or insured housing requirements in 24 CFR 5.105(a)(2) apply to this part.

PART 1006—NATIVE HAWAIIAN HOUSING BLOCK GRANT PROGRAM

■ 7. The authority citation for 24 CFR part 1006 continues to read as follows:

Authority: 25 U.S.C. 4221 *et seq.;* 42 U.S.C. 3535(d).

■ 8. Amend § 1006.355 to read as follows:

■ a. The undesignated paragraph is revised and designated as paragraph (a);

■ b. Redesignate paragraphs (a), (b), and (c) as paragraphs (a)(1), (a)(2), and (a)(3);

■ c. Redesignate paragraphs (c)(1) and (c)(2) as paragraphs (a)(3)(i) and (a)(3)(ii); and

■ d. Add paragraph (a)(4)

§ 1006.355 Nondiscrimination requirements.

(a) Program eligibility under the Act and this part may be restricted to Native Hawaiians. Subject to the preceding sentence, no person may be discriminated against on the basis of race, color, national origin, religion, sex, familial status, or disability, or excluded from program eligibility because of actual or perceived sexual orientation, gender identity, or marital status. The following nondiscrimination requirements are applicable to the use of NHHBG funds:

* * * * *

(4) The equal access to HUD-assisted or insured housing requirements in 24 CFR 5.105(a)(2).

(b) [RESERVED]

PART 1007—SECTION 184A LOAN GUARANTEES FOR NATIVE HAWAIIAN HOUSING

■ 9. The authority citation for 24 CFR part 1007 continues to read as follows:

Authority: 12 U.S.C. 1715z–13b; 15 U.S.C. 1639c; 42 U.S.C. 3535(d).

■ 10. Amend § 1007.45 to revise the heading, designate the undesignated paragraph as paragraph (a), and add paragraph (b) to read as follows:

§ 1007.45 Nondiscrimination

(a) * * *

(b) The equal access to HUD-assisted or insured housing requirements in 24 CFR 5.105(a)(2) apply to this part.

Dated: March 30, 2016.

Lourdes Castro Ramirez,

Principal Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2016–10753 Filed 5–6–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 71

[Docket ID: DOD–2013–OS–0181]

RIN 0790–AJ13

Eligibility Requirements for Minor Dependents To Attend DoD Domestic Dependent Elementary and Secondary Schools (DDESS)

AGENCY: Under Secretary of Defense for Personnel and Management, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule updates policy and procedures for minor dependents attending schools operated by DOD pursuant to 10 U.S.C. 2164. The proposed rule outlines procedures for eligibility, application and enrollment in DOD schools and describes procedures for reimbursement of educational services. This proposed rule discusses provision for the elementary and secondary education to minor dependents of members of the armed forces and civilian employees of the Federal Government residing within the United States (including the territories, commonwealths, and possessions of the United States).

DATES: Comments must be received by July 8, 2016.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Marsha Jacobson, 571–372–1900.

SUPPLEMENTARY INFORMATION: The Federal government has provided educational services to the dependent children of Federal employees residing on Federal military installations under various legal authorities and Federal statutes since 1820. In 1950, schools were established on military installations under section 6 of Public Law 81–874, Impact Aid Act (codified at 20 U.S.C. 241). In 1994, Congress repealed Public Law 81–874 and passed Public Law 103–337, the FY1995 National Defense Authorization Act (codified at 10 U.S.C. 2164), creating the Domestic Dependent and Elementary and Secondary Schools (DDESS). Under 10 U.S.C. 2164, the Department of Defense operates approximately 65 elementary and secondary schools on federal installations in the United States and its territories, possessions, and commonwealths.

Since the passage of 10 U.S.C. 2164 in 1994, Congress has passed a number of minor changes to the statute's eligibility provisions in order to provide DDESS with the flexibility to meet developing real-world contingencies. While the overall student enrollment in DDESS schools has declined in recent years as a result of the reductions in the military force, the statutory changes have minimally expanded eligibility to certain categories of personnel.

These categories of personnel include the dependents of military personnel killed in combat-related operations (*i.e.,* fallen soldiers); the dependents of wounded and injured military personnel receiving medical care at military hospitals on installations with DDESS schools (*i.e.* wounded warriors); and to students enrolled in an overseas DoD school who have been required to depart the overseas location as a result of an evacuation order. Given the overall decline in student enrollment associated with the reduction of the military force, there are no additional costs associated with this rulemaking which only reflects the statutory changes to student eligibility.

Childhood education is essential, and DoD is determined to provide primary and secondary education for dependent children of members of the armed forces and civilian employees of the Federal Government residing on military installations.

This proposed rule updates the eligibility requirements and the policy and procedures for minor dependents attending schools operated by DOD pursuant to 10 U.S.C. 2164. The proposed rule outlines procedures for eligibility, application, and enrollment in DOD schools and describes procedures for reimbursement of educational services. The proposed rule applies to schools (prekindergarten through grade 12) operated by the Department of Defense within the United States (including the territories, commonwealths, and possessions of the United States).

This proposed rule also describes procedures for participation of eligible dependents in the DoDEA Virtual School (*i.e.*, DoDEA's on-line school).

Costs and Benefits:

The total operating costs for the DDESS schools for FY15 is $383.1M. Relative to the baseline of the Department of Defense Instruction 1342.26 where policies and responsibilities for enrollment of certain dependents in arrangements operated by or entered into by the Department of Defense pursuant to 10.U.S.C. 2164 are specified, the incremental costs associated with increasing the eligibility criteria is expected to be zero. This program is not a transfer program since the education of these dependents would not be assumed by the state governments where these military installations are located. The benefits of providing a tuition free education to certain dependents of members of the armed forces and civilian employees on military installations in the United States (including the territories, commonwealths, and possessions of the United States) remain the same.

Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget (OMB) under the requirements of these Executive orders.

Section 202, Public Law 104–4, "Unfunded Mandates Reform Act"

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This proposed rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

Public Law 96–354, "Regulatory Flexibility Act" (5 U.S.C. 601)

The Department of Defense certifies that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Public Law 96–511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

Section 71.6(f) of this proposed rule contains information collection requirements. DoD has submitted the following proposal to OMB under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed information collection; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

Title: Eligibility Requirements for Minor Dependents to Attend DoD Domestic Dependent Elementary and Secondary Schools (DDESS).

Type of Request: New.

Number of Respondents: 23,000.

Responses per Respondent: 1.

Annual Responses: 23,000.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 5.750.

Needs and Uses: Department of Defense Instruction 1342.26 establishes policy and assigns responsibilities for enrollment of certain dependents in arrangements operated by or entered into by the Department of Defense pursuant to 10 U.S.C. 2164. Pursuant to this legislation, the Secretary of Defense is authorized to enter into arrangements to provide for the elementary and secondary education of certain members of the armed forces and civilian employees of the Federal Government residing within the United States (including the territories, commonwealths, and possessions of the United States). Authority to operate these schools or arrangements has been delegated by the Secretary of Defense to the Department of Defense Education Activity (DoDEA) Domestic Dependent Elementary and Secondary Schools (DDESS). The operating statute, 10 U.S.C. 2164, requires (1) students to be dependents of members of the armed forces or dependents of civilian employees of the Federal government residing on a military installation in the United States (including territories, commonwealths, and possessions of the United States or (2) students to be dependents of members of the armed forces or dependents of civilian employees of the Federal government residing in a territory, commonwealth, or possession of the United States but not on a military installation. In order to determine eligibility for enrollment it is necessary for the agency collect information from each sponsor to prove dependency, employment and residential status on a school year basis.

Affected Public: Individuals or Households.

Frequency: On Occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov,* with a copy to the Department of Defense Education Activity, 4800 Mark Center Drive, Alexandria, VA 22350. Comments can be received from 30 to 60 days after the date of this notice, but comments to OMB will be most useful if received by OMB within 30 days after the date of this notice.

You may also submit comments, identified by docket number and title, by the following method:

* *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Marsha Jacobson, Department of Defense Education Activity, 4800 Mark Center Drive, Alexandria, VA 22350.

Executive Order 13132, "Federalism"

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 71

Aid to families with dependent children, Elementary and secondary education, Minors.

■ Accordingly, 32 CFR part 71 is proposed to be added to read as follows:

PART 71—ELIGIBILITY REQUIREMENTS FOR MINOR DEPENDENTS TO ATTEND DOD DOMESTIC DEPENDENT ELEMENTARY AND SECONDARY SCHOOLS (DDESS)

Sec.
71.1 Purpose.
71.2 Applicability.
71.3 Definitions.
71.4 Policy.
71.5 Responsibilities.
71.6 Procedures.

Authority: 5 U.S.C. 2103, 10 U.S.C. 2164, 31 U.S.C. 1535.

§ 71.1 Purpose.

This part establishes policy assigns responsibilities for enrollment in arrangements (as defined in § 71.3) operated by or entered into by the DoD in accordance with DoD Directive 1342.20 and 10 U.S.C. 2164.

§ 71.2 Applicability.

This part applies to:

(a) The Office of the Secretary of Defense, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this part as the "DoD Components").

(b) Arrangements operated by or entered into by the DoD within the United States (including the territories, commonwealths, and possessions of the United States).

(c) Dependent children of active duty military members (as defined in § 71.3) and civilian employees of the Federal Government enrolled or seeking enrollment in arrangements.

(d) Dependent children of members of a foreign armed force assigned to and residing on a U.S. military installation enrolled or seeking enrollment in arrangements.

(e) Dependent children of employees of the American Red Cross residing in Puerto Rico enrolled or seeking enrollment in DDESS arrangements in Puerto Rico.

(f) Non-DoD federal agencies seeking enrollment of dependent children of full-time employees in arrangements on an agency reimbursable basis as determined by the Secretary of Defense.

§ 71.3 Definitions.

These terms and their definitions are for the purposes of this part.

Active duty military member. A member of the Military Services who has been ordered to:

(1) Active duty for at least 365 consecutive days in accordance with 10 U.S.C. 2164 or title 14, U.S.C.; or

(2) Full-time National Guard duty for at least 365 consecutive days in accordance with title 32, U.S.C.

Arrangement. Actions taken by the Secretary of Defense to provide education to dependent children of active duty military members and civilian employees of the Federal Government pursuant to DoD Directive 1342.20 and 10 U.S.C. 2164, through either DDESS arrangements or DDESS special arrangements.

Combat-related operation. An operation in which members of the Military Services are or may become involved in military actions, operations, or hostilities against an enemy of the United States or against an opposing military force.

DDESS arrangement. A school operated by the DoD pursuant to DoD Directive 1342.20 and 10 U.S.C. 2164 and provides a free public education for eligible children. This does not include the DoDEA Virtual School.

DDESS special arrangement. An agreement made pursuant to 10 U.S.C. 2164 and DoD Directive 1342.20 between the DoD and a local educational agency where a school or a school system operated by the local educational agency provides educational services to eligible dependent children of active duty military members and full time DoD civilian employees. Arrangements result in partial or total federal funding to the education agency for the educational services provided.

Dependent child. An unmarried child under the age of 21, who resides with the sponsor and:

(1) Is the child of the sponsor, including an adopted child or step-child (but not after the divorce of the member from the stepchild's natural parent);

(2) Has been placed in the sponsor's home by a local, State, or foreign government placement agency or a government-approved process, provided the sponsor produces a document from such an agency establishing the fact of relationship and the effective date of the relationship;

(3) The sponsor has acknowledged, in writing, that the child is a full-time resident in the sponsor's household, the sponsor is providing more than one-half of the child's support, and the sponsor accepts financial and educational responsibility for the child as if the child were the sponsor's natural or legally adopted child; or

(4) Has been placed in the custody of the sponsor by a court of competent jurisdiction in the United States and:

(i) Is dependent on the sponsor for more than one-half of the person's support.

(ii) Is not a dependent of any sponsor in accordance with any other part of this definition.

DoDEA Virtual School: A virtual school operated by the Department of Defense in accordance with DoD Directive 1342.20 and 10 U.S.C. 2164 to provide a free public education for eligible dependent children using an online platform.

Good cause. Consistent with the national interest, as approved by the Secretary of Defense. Such cause would permit the continued enrollment of a dependent child in a DDESS arrangement in situations such as when the child has only 1 year of school remaining or other such meritorious situations.

Injured. To suffer physical harm or damage to a part of one's body. Any harm or damage that is done or sustained. A condition caused by trauma, such as fracture, wound, sprain, dislocation, concussion, or compression. Also, an injury includes conditions resulting from extremes of temperatures or prolonged exposure. Acute poisonings resulting from exposure to a toxic or poisonous substance are also classed as injuries.

Line of duty. A finding after all available information has been reviewed that determines an injury, illness, or disease was incurred or aggravated while in an authorized duty status and was not due to gross negligence or misconduct of the member.

Professional, excepted service employee. An excepted service employee, as defined in 5 U.S.C. 2103, who holds a valid license or certificate from governmental agency or professional body attesting to professional proficiency or knowledge (*e.g.*, teacher, counselor, administrator, nurse, professional engineer, psychologist, media specialist, therapist) as certified by the agency.

Sponsor. An active duty military member or civilian employee of the Federal Government seeking to enroll a dependent child in an arrangement.

§ 71.4 Policy.

It is DoD policy that arrangements are operated or entered into in accordance with 10 U.S.C. 2164. Enrollment is limited to eligible dependent children of active duty military members, DoD civilian employees, members of a foreign armed force, and certain employees of the American Red Cross residing in Puerto Rico, or non-DoD federal agencies seeking enrollment of dependent children of full-time employees in arrangements on an agency reimbursable basis as determined by the Secretary of Defense.

§ 71.5 Responsibilities.

(a) The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) ensures that the DDESS program fosters optimum communication on matters relating to DoDEA eligibility requirements for DDESS within DoDEA and the Military Departments.

(b) Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Readiness and Force Management (ASD(R&FM)) monitors compliance with this part.

(c) Under the authority, direction, and control of the ASD(R&FM), the Director, DoD Education Activity (DoDEA):

(1) Makes determinations of eligibility for enrollment in arrangements. Decisions by the Director, DoDEA, on requests to enroll dependents in arrangements in accordance with this part are final.

(2) Monitors implementation and compliance with this part.

(3) Ensures arrangements allow only those students authorized by this part to enroll in arrangements.

§ 71.6 Procedures.

(a) In compliance with paragraph (f) of this section, DDESS arrangements within the United States will:

(1) Provide a tuition-free education to the dependent children of:

(i) Active duty military members residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(ii) Full-time civilian DoD employees residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(iii) A deceased member of the Military Services who died in the line of duty in a combat-related operation. The operation must have been designated as combat-related by the Secretary of Defense and the dependent children must reside on or near a military installation served by a DDESS arrangement.

(iv) A member of a foreign armed force residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(v) Active duty military members occupying temporary housing, regardless of whether the housing is on federal property, when the Secretary of Defense has determined that the circumstances justify extending the enrollment authority to include the dependents, including:

(A) When adequate living quarters are unavailable on the military installation to which the active duty military member is assigned. Eligibility in accordance with this provision extends only to dependent children of active duty military members assigned by official orders to a military installation served by a DDESS arrangement.

(B) While the active duty military member is wounded, ill or injured. Eligibility in accordance with this provision extends only to dependent children of active duty military members assigned by official orders to a military installation served by a DDESS arrangement.

(vi) Active duty military members and federal employees overseas whose enrolled dependents have been evacuated and relocated within a reasonable commuting distance of an arrangement in accordance with the criteria set forth in subsection (k) of 10 U.S.C. 2164.

(2) Provide education on an agency-reimbursable basis to dependent children of full-time civilian employees of non-DoD federal agencies residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(b) In compliance with paragraph (f) of this section, DDESS special arrangements within the United States will:

(1) Provide a tuition-free education to the dependent children of:

(i) Active duty military members residing in permanent living quarters for any part of the school year on a military installation served by a DDESS special arrangement.

(ii) Full-time civilian DoD employees residing in permanent living quarters for any part of the school year on a military installation served by a DDESS special arrangement.

(iii) A deceased member of the Military Services who died in the line of duty in a combat-related operation. The operation must have been designated as combat-related by the Secretary of Defense and the dependent children must reside on a military installation served by a DDESS special arrangement.

(iv) A member of a foreign armed force residing in permanent living quarters for any part of the school year on a military installation served by a DDESS special arrangement.

(2) Provide education on an agency reimbursable basis to dependent children of full-time civilian employees of non-DoD federal agencies residing in permanent living quarters for any part of the school year on a military installation served by a DDESS special arrangement.

(c) In compliance with paragraph (f) of this section, DDESS arrangements within a territory, commonwealth, or possession of the United States will:

(1) Provide a tuition-free education to dependent children of:

(i) Active duty military members residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(ii) Full-time civilian DoD employees residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(iii) A deceased member of the Military Services who died in the line of duty in a combat-related operation. The operation must have been designed as combat-related by the Secretary of Defense and the dependent children must reside on or near a military installation served by a DDESS arrangement.

(iv) A member of a foreign armed force residing in permanent living quarters for any part of the school year on any military installation served by a DDESS arrangement.

(v) Active duty military members stationed or home-ported in a territory, commonwealth, or possession of the United States and not residing in permanent living quarters on a military installation. Eligibility in accordance with this provision extends only to dependent children of active duty military members assigned by official orders to a military installation served by a DDESS arrangement.

(vi) Full-time civilian DoD employees, not residing in permanent living quarters on a military installation, who are subject by policy and practice to transfer or reassignment to a location where English is the language of instruction in the schools normally attended by dependent children of federal personnel. Dependents in this category may not be enrolled in the DDESS arrangement for more than 5 consecutive school years, unless:

(A) The Secretary of Defense, for good cause (as defined in § 71.3), extends the period; or

(B) Admission is granted based on eligibility in accordance with paragraph (c)(1)(vii) of this section.

(vii) Full-time, professional, excepted service employees (as defined in § 71.3) of the DDESS arrangement not residing in permanent quarters on a military installation.

(viii) Active duty military members, whose dependents reside on or off any military installation served by a DDESS arrangement with the dependents' designated location being in a territory, commonwealth, or possession of the United States, and who are assigned to:

(A) A remote location;

(B) A dependents' restricted unaccompanied tour of duty; or

(C) Unusually arduous sea duty.

(2) Provide education on an agency reimbursable basis to dependent children of:

(i) Full-time civilian employees of the non-DoD federal agencies residing in permanent living quarters for any part of the school year on a military installation served by a DDESS arrangement.

(ii) Full-time civilian employees of the United States Immigration and Customs Enforcement and the United States Customs and Border Protection residing in Puerto Rico.

(iii) Full-time civilian employees of non-DoD federal agencies not residing in permanent living quarters on a military installation, who are subject by policy and practice to transfer or reassignment to a location where English is the language of instruction in the schools normally attended by dependent children of federal personnel, when the Secretary of Defense determines that the circumstances of such living arrangements justify extending the enrollment authority to include the dependents. Dependents in this category may not be enrolled in the DDESS arrangement for more than 5 consecutive school years, unless the Secretary of Defense extends the period for good cause.

(iv) Full-time employees of the American Red Cross residing in Puerto Rico and performing emergency services on behalf of active duty military members.

(d) In compliance with paragraph (f) of this section, DDESS special arrangements within a territory, commonwealth, or possession of the United States will:

(1) Provide a tuition-free education to dependent children of:

(i) Active duty military members residing in permanent living quarters for any part of the school year on a military installation served by a DDESS special arrangement.

(ii) Full-time civilian DoD employees residing in permanent living quarters for any part of the school year on a military installation served by a DDESS special arrangement.

(iii) A deceased member of the Military Services who died in the line of duty in a combat-related operation. The operation must have been designated as combat-related by the Secretary of Defense and the dependent children must live in an area served by a DDESS special arrangement.

(iv) A member of a foreign armed force residing in permanent living quarters for any part of the school year on any military installation served by a DDESS special arrangement.

(v) Active duty military members stationed or home-ported in a territory, commonwealth, or possession of the United States and not residing in permanent living quarters on a military installation. Eligibility in accordance with this provision extends only to dependent children of active duty military members assigned by official orders to an area served by a DDESS special arrangement.

(vi) Full-time civilian DoD employees, not residing in permanent living quarters on a military installation but residing in an area served by a DDESS special arrangement, who are subject by policy and practice to transfer or reassignment to a location where English is the language of instruction in the schools normally attended by dependent children of federal personnel. Dependents in this category may not be enrolled in the DDESS special arrangement for more than 5 consecutive school years, unless the Secretary of Defense, for good cause, extends the period.

(vii) Active duty military members, whose dependents' reside in the area served by a DDESS special arrangement, with the dependents' designated location being in a territory, commonwealth, or possession of the United States who are assigned to:

(A) A remote location,

(B) A dependents' restricted unaccompanied tour of duty, or

(C) Unusually arduous sea duty.

(2) Provide education on an agency-reimbursable basis to dependent children of:

(i) Full-time civilian employees of non-DoD federal agencies residing in permanent living quarters for any part of the school year on any military installation served by a DDESS special arrangement.

(ii) Full-time civilian employees of the United States Immigration and Customs Enforcement and the United States Customs and Border Protection residing in Puerto Rico.

(e) In compliance with paragraph (f) of this section, the DoDEA Virtual School shall:

(1) Provide a tuition-free education to eligible dependent children currently enrolled in DDESS arrangements in accordance with paragraphs (a) and (c) of this section.

(2) Provide coursework on a tuition paying basis to dependent children of members of the Military Services on active duty who:

(i) Are enrolled in an elementary or secondary school operated by a local education agency (LEA) or other accredited educational program in the United States, and

(ii) Who immediately prior to such enrollment, were enrolled in an elementary or secondary school operated by the Department of Defense Dependents School (DoDDS).

(f) Procedures for application and enrollment:

(1) Application for enrollment will be made to the arrangement to which

admission is sought. The active duty military member or civilian employee sponsoring the dependent child(ren) must provide proof of status upon which the requested admission is based. DDESS reserves the right to request additional information, should it be deemed necessary to make a determination of eligibility.

(2) Eligibility based on residency on a military installation may be established by:

(i) Actual residence in permanent quarters on a military installation served by an arrangement; or

(ii) Written affirmation provided by the installation family housing manager that the sponsor has applied for and will be able to occupy permanent quarters on the military installation within 90 school days (or 180 school days if an exception for the installation has been approved by the Secretary of Defense) after the sponsor reports to the new duty station. Enrollment occurring pursuant to this paragraph obligates the sponsor to accept permanent quarters on the military installation when available and offered or the dependent child's eligibility to attend the arrangement terminates.

(3) Eligibility for dependent children of full-time employees of the Federal Government, will be established in accordance with these provisions:

(i) The sponsor seeking enrollment will provide proof of full-time employment with the Federal Government, or the agency employing the civilian sponsor will provide a written statement confirming the sponsor's position meets the eligibility requirements.

(ii) The written statement must be signed by the agency's Director of Personnel or principal administrative officer at its main headquarters.

(iii) Federal government employees residing in a territory, commonwealth, or possession of the United States seeking to continue the enrollment of their dependent(s) in a DDESS arrangement for more than 5 consecutive years pursuant to paragraph (a)(1)(v)(C), (c)(2)(iii), or (d)(1)(vi) of this section must submit a request for an exception to policy. The request must be made in writing and submitted through the employee's agency to the Director, DDESS, for consideration. The request must be received by the Director, DDESS before the start of the school year for which the exception is requested and must provide information showing that in the interest of the dependent's educational well-being, good cause exists for granting the exception. Reimbursement shall be obtained when required 10 U.S.C. 2164 (c)(2)(B).

(4) The sponsor seeking enrollment of a dependent child in the DoDEA Virtual School under paragraph (e)(2) of this section shall provide proof that:

(i) The dependent is currently enrolled in an elementary or secondary school operated by an LEA or other accredited educational program in the United States;

(ii) Immediately prior to enrollment in the LEA or other accredited educational program, the dependent was enrolled in an elementary or secondary school operated by DoDDS;

(iii) The LEA or other accredited educational program does not offer the requested coursework or extenuating circumstances exist to justify enrolling the dependent in the DoDEA Virtual School; and

(iv) The course(s) through the DoDEA Virtual School are taken for credit, or extenuating circumstances exist to justify enrolling the dependent in the DoDEA Virtual School.

(g) The Secretary of Defense may permit a currently enrolled student to continue:

(1) For the remainder of the year, if the status of the sponsor of a currently enrolled student changes so that the dependent child would no longer be eligible for enrollment in an arrangement.

(2) Beyond the current school year in a DDESS arrangement notwithstanding a change in the status of the sponsor which would otherwise terminate eligibility for good cause. Requests for continuation of enrollment, beyond the end of the school year, for good cause, must be in writing and submitted to the Director, DDESS. A good cause authorization for continued enrollment will cover only one school year at a time.

(h) Procedures for reimbursement of educational services:

(1) All non-DoD federal agencies whose employees enroll a dependent in an arrangement pursuant to 10 U.S.C. 2164 will reimburse the DoD for the cost of educational services provided on a school year basis.

(2) The non-DoD federal agency will certify school-aged dependents for their employees no later than May 1st each year for the following school year.

(3) DoDEA resource management (RM) will publish the ensuing school year's educational services tuition rates on or before May 31st each year.

(4) Each June, upon receipt of an official list of eligible employees and their school-aged dependents from the DDESS arrangement, DDESS RM will send each agency a tuition reimbursement notification letter for the entire upcoming school year. Tuition reimbursement payments from the agencies will be due by August of that school year for the first grading period and due by October for the remaining grading periods. These educational services are considered severable and subject to the provisions of 31 U.S.C. 1535, also known and referred to in this part as the "Economy Act".

(5) At the beginning of each fiscal year, DoDEA RM allocates a portion of the agency's annual tuition reimbursement authority to DDESS, which grants explicit permission to collect and retain tuition reimbursements that directly offset agency operating expenses for providing educational services.

(6) Federally funded agencies are required to establish an interagency agreement with DDESS. This agreement serves as the authority for the Defense Finance and Accounting Service (DFAS) to centrally bill or transfer funds between the ordering agency and the provider of educational services based on DDESS tuition collection billings and refunds. DFAS will process reimbursable payment transactions via the Intra-Governmental Payment and Collection system.

(i) Procedures for payment of tuition for educational services provided by DoDEA Virtual School

(1) All members of the Military Services on active duty seeking to enroll dependents in the DoDEA Virtual School pursuant to paragraph (e)(2) of this section will pay tuition to the Department of Defense for the cost of the educational services provided.

(2) Tuition is based on the average market rate for virtual courses offered to the public in the U.S.

(3) DoDEA RM will publish the ensuing school year's educational services tuition rates on or before May 31st of each year.

(4) Tuition must be paid prior to enrollment.

(5) Tuition payments are reimbursable up to three weeks after enrollment in the DoDEA Virtual School on a pro-rated basis.

Dated: May 4, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–10821 Filed 5–6–16; 8:45 am]

BILLING CODE 5001–06–P

Notices

Federal Register
Vol. 81, No. 89
Monday, May 9, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. Number AMS–FV–10–0047, FV–16–330]

United States Standards for Grades of Cauliflower

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is proposing to revise the United States Standards for Grades of Cauliflower. The current U.S. grade standards do not have provisions for grading purple, orange, or green cauliflower. The proposed revision would amend the color requirement to allow all colors of cauliflower to be certified to a U.S. grade. In addition, AMS proposes to amend the size requirement to allow curds less than 4 inches in diameter to be certified to a grade; to add marking requirements to sizes less than 4 inches in diameter; and, to remove the unclassified section.

DATES: Comments must be received by July 8, 2016.

ADDRESSES: Interested persons are invited to submit written comments to the Standardization Branch, Specialty Crops Inspection Division, Specialty Crops Program, Agricultural Marketing Service, U.S. Department of Agriculture, National Training and Development Center, Riverside Business Park, 100 Riverside Parkway, Suite 101, Fredericksburg, VA 22406; fax: (540) 361–1199; or, via the web at: *www.regulations.gov.* Comments should reference the dates and page number of this issue of the **Federal Register** and will be made available for public inspection in the above office during regular business hours. Comments can also be viewed as submitted, including any personal information you provide, on the *www.regulations.gov* Web site. A copy of the proposed revised United States Standards for Grades of Cauliflower is located at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dave Horner at the address above, or at phone (540) 361–1128; fax (540) 361–1199; or, email *Dave.Horner@ams.usda.gov.* Copies of the proposed U.S. Standards for Grades of Cauliflower are available on the Internet at *http://www.regulations.gov.* The current U.S. Standards for Grades of Cauliflower are available on the Specialty Crops Inspection Division Web site at *http://www.ams.usda.gov/grades-standards/cauliflower-grades-and-standards.*

SUPPLEMENTARY INFORMATION: Section 203(c) (7 U.S.C. 1622(c)) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices." AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables not connected with Federal marketing orders or U.S. import requirements no longer appear in the Code of Federal Regulations, but are maintained by USDA, AMS, Specialty Crops Program, and are available on the internet at *http://www.ams.usda.gov/grades-standards.*

AMS proposes to revise the voluntary United States Standards for Grades of Cauliflower using the procedures that appear in Part 36, Title 7 of the Code of Federal Regulations (7 CFR part 36). These standards were last revised March 15, 1968.

Background and Comments

On February 9, 2012, AMS published a notice in the **Federal Register** (77 FR 6772) soliciting comments on proposed revisions to the United States Standards for Grades of Cauliflower. AMS received one comment from an agricultural trade association. The agricultural trade association stated that by number, but not necessarily by volume, cauliflower growers supported the proposed revision. However, members expressed some confusion about the meaning of "unless otherwise specified" in regards to size, and requested clarification. Following the comment period, AMS determined it would not proceed with the revisions as proposed.

The U.S. grade standards presently require cauliflower curds to be white, creamy white, or cream color, but do not have provisions for grading other colors of cauliflower. AMS proposes to amend U.S. No. 1 color provisions by adding "unless otherwise specified" to the basic requirement for color. The phrase "unless otherwise specified" in regards to color would be interpreted as follows: When colors other than white, creamy white, or cream color are specified, those colors could be certified to a grade. Likewise, when designated as a mixed-color pack, a grade could be applied to all the colors in the pack, not just to the curds that are white, creamy white, or cream color. For example, a grade could be applied to a pack containing a green, an orange, a purple, and a white cauliflower curd when specified as a mixed-color pack. AMS applies the phrase "unless otherwise specified," or similar terminology, to potatoes, peppers, and other commodities to allow other colors, or the comingling of colors, to be certified to a grade. This revision would also affect the U.S. Commercial grade.

Previously, in 2012, AMS proposed to add "unless otherwise specified" to the size requirement for the U.S. No. 1 grade to allow for smaller sizes. This too is a common practice for potatoes, onions, and many other commodities. However, after contacting the agricultural trade association, AMS discovered that they were concerned that unmarked containers with curds smaller than 4 inches may lose their specified designation after being resold to another party. For example, the original verbal or contractual agreement might not follow the product through the marketing chain. At final destination, unmarked product may fail to grade U.S. No. 1, since the cauliflower curds would be smaller than 4 inches in diameter.

Therefore, AMS now proposes to amend the U.S. No. 1 size provisions for cauliflower heads by adding "unless marked to a maximum diameter of less than 4 inches. Cauliflower curds marked less than 4 inches may not be comingled with cauliflower curds packed to be 4 inches or larger." to the basic requirement for curd size. To explain the marking requirements, AMS proposes to add a new "§ 51.556 Marking Requirements," which would read as follows: "When the product is packed to be less than 4 inches in maximum diameter, 90 percent or more of the master containers shall be plainly stamped, printed, labeled or otherwise marked with the maximum diameter. The term 'maximum' or its recognized abbreviation, when following a diameter size marking, means that the curds are of the size marked or smaller." The current § 51.556, Metric Conversion Table, will be redesignated as § 51.557.

The size revision and marking requirements would be interpreted as follows: When cauliflower curds are specified to be less than 4 inches in maximum diameter, at least 90 percent of the master containers in a lot must be marked by a maximum diameter of less than 4 inches. For example, a lot having curds no larger than 3½ inches in diameter must have 90 percent or more of the master containers marked 3½" max. If less than 90 percent of the master containers are marked, the lot may meet grade requirements but would fail to meet marking requirements as to size.

Furthermore, curds that are specified to be less than 4 inches in maximum diameter would not include cauliflower florets, since florets are pieces of curd and not considered small heads of cauliflower. Therefore, florets would not be certified to a grade.

This revision would also affect the U.S. Commercial grade.

The agricultural trade association had no objection to removing the "Unclassified" category from the standards. The unclassified section is being removed from all standards when they are revised. This category is not a grade and only serves to show that no grade has been applied to the lot. It is no longer considered necessary.

AMS believes that permitting all colors, mixed-color packs, and smaller sizes of cauliflower to be certified to a grade reflects current marketing practices and consumer demand, and will facilitate the marketing of cauliflower by providing the industry with more flexibility.

The official grade of a lot of cauliflower covered by these standards will be determined by the procedures set forth in the Regulations Governing Inspection, Certification, and Standards of Fresh Fruits, Vegetables and Other Products (Sec. 51.1 to 51.61).

This notice provides a 60-day period during which interested parties may comment on the proposed revisions to the standards. This period is deemed appropriate in order to implement these changes, if adopted, as soon as possible to reflect current marketing practices.

Authority: 7 U.S.C. 1621–1627.

Dated: May 3, 2016.

Elanor Starmer,

Administrator.

[FR Doc. 2016–10741 Filed 5–6–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Office of the Under Secretary, Research, Education, and Economics; Notice of the Advisory Committee on Biotechnology and 21st Century Agriculture Meeting

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2, the United States Department of Agriculture announces a meeting of the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21). The committee is being convened to: consider work of the three *ad hoc* subgroups on the progress of their analyses relevant to the new AC21 charge; discuss a draft outline for the committee's next report and selected draft content, including a draft guidance document for producers and a draft model for facilitating local conversations around coexistence; and continue overall discussions on the committee charge and planning the completion of its work.

DATES: The meeting will be held on Monday–Tuesday, June 13–14, 2016, 8:30 a.m. to 5:00 p.m. each day. This meeting is open to the public. On June 13, 2016, if time permits, reasonable provision will be made for oral presentations of no more than five minutes each in duration, starting at 3:30 p.m. Members of the public who wish to make oral statements should also inform Dr. Schechtman in writing or via Email at the indicated addresses below at least three business days before the meeting.

ADDRESSES: U.S. Access Board Conference Room, 1331 F Street NW., Suite 800, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: General information about the committee can also be found at *http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH_AC21&navtype=RT&parentnav=BIOTECH.* However, Michael Schechtman, Designated Federal Official, Office of the Deputy Secretary, USDA, 202B Jamie L. Whitten Federal Building, 12th and Independence Avenue SW., Washington, DC 20250; Telephone (202) 720–3817; Fax (202) 690–4265; Email *AC21@ars.usda.gov* may be contacted for specific questions about the committee or this meeting.

SUPPLEMENTARY INFORMATION: The AC21 has been established to provide information and advice to the Secretary of Agriculture on the broad array of issues related to the expanding dimensions and importance of agricultural biotechnology. The committee is charged with examining the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and providing guidance to USDA on pressing individual issues, identified by the Office of the Secretary, related to the application of biotechnology in agriculture. In recent years, the work of the AC21 has centered on the issue of coexistence among different types of agricultural production systems. The AC21 consists of members representing the biotechnology industry, the organic food industry, farming communities, the seed industry, food manufacturers, state government, consumer and community development groups, as well as academic researchers and a medical doctor. In addition, representatives from the Department of Commerce, the Department of Health and Human Services, the Environmental Protection Agency, the Council on Environmental Quality, and the Office of the United States Trade Representative serve as "ex officio" members.

In its last report, issued on November 17, 2012, entitled "Enhancing Coexistence: A Report to the Secretary of Agriculture," and available on the Web site listed below, the AC21 offered a diverse package of recommendations, among which was a recommendation that ". . . USDA should facilitate development of joint coexistence plans by neighboring farmers," and that in a pilot program, USDA should, among other things, offer incentives for the development of such plans.

At its meeting on December 14–15, 2015, USDA offered a specific new charge to the AC21 building on its previous work. Recognizing that USDA currently lacks the legal authority to offer any such incentives, the committee has been charged with considering the following two questions: Is there an approach by which farmers could be encouraged to work with their neighbors to develop joint coexistence plans at the State or local level? If so, how might the

Federal government assist in that process?

At the AC21's last meeting, on March 14–15, 2016, AC21 members reached a general agreement on the main content elements of the upcoming report. In devising their approach to respond to this charge, the AC21 has established 3 *ad hoc* subgroups to gather and analyze information and options for the full committee's consideration. These address: development of a guidance document which could be made available to farmers and other stakeholders; potential models for facilitating conversations around coexistence and potential available incentives; and potential venues and conveners of coexistence conversations.

The three objectives for the meeting are:

- To consider work of the three *ad hoc* subgroups on the progress of their analyses relevant to the new AC21 charge;
- to discuss a draft outline for the committee's next report and selected draft content, including a draft guidance document for producers and a draft model for facilitating local conversations around coexistence; and
- to continue overall discussions on the committee charge and planning the completion of its work.

Background information regarding the work and membership of the AC21 is available on the USDA Web site at *http://www.usda.gov/wps/portal/usda/usdahome?contentid=AC21Main.xml&contentidonly=true.*

Register for the Meeting: The public is asked to pre-register for the meeting at least 10 business days prior to the meeting. Your pre-registration must state: the names of each person in your group; organization or interest represented; the number of people planning to give oral comments, if any; and whether anyone in your group requires special accommodations. Submit registrations to Ms. Dianne Fowler at (202) 720–4074 or by Email at *Dianne.fowler@ars.usda.gov* by May 25, 2016. The Agricultural Research Service will also accept walk-in registrations. Members of the public who request to give oral comments to the Committee, must arrive by 8:45 a.m. on June 13, 2016 and will be given their allotted time limit and turn at the check-in table.

Public Comments: Written public comments may be mailed to Michael Schechtman, Designated Federal Official, Office of the Deputy Secretary, USDA, 202B Jamie L. Whitten Federal Building, 12th and Independence Avenue SW., Washington, DC 20250; via fax to (202) 690–4265 or email to *AC21@ars.usda.gov.* All written comments must arrive by June 8, 2016. Oral comments are also accepted. To request to give oral comments, see instructions under "Register for the Meeting" above.

Availability of Materials for the Meeting: All written public comments will be compiled into a binder and available for review at the meeting. Duplicate comments from multiple individuals will appear as one comment, with a notation that multiple copies of the comment were received. Please visit the Web site listed above to learn more about the agenda for or reports resulting from this meeting.

Meeting Accommodations: The meeting will be open to the public, but space is limited. USDA is committed to ensuring that all employees are included in our work environment, programs and events. If you are a person with a disability and request reasonable accommodations to participate in this meeting, please note the request in your registration. All reasonable accommodation requests are managed on a case by case basis.

Issued at Washington, DC, this 2nd day of May.

Ann M. Bartuska,

Deputy Under Secretary, Research, Education and Economics.

[FR Doc. 2016–10807 Filed 5–6–16; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2016–0015]

Notice of Request To Renew an Approved Information Collection (Import of Undenatured Inedible Product)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to renew the approved information collection regarding the importation of undenatured inedible meat and egg products into the United States. The approval for this information collection will expire on August 31, 2016.

DATES: Submit comments on or before July 8, 2016.

ADDRESSES: FSIS invites interested persons to submit comments on this information collection. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2016–0015. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6065, South Building, Washington, DC 20250; (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Title: Import of Undenatured Inedible Product.

OMB Control Number: 0583–0161.

Type of Request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary of Agriculture (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). FSIS protects the public by verifying that meat and egg products are safe, wholesome, not adulterated, and correctly labeled. FSIS is planning to request a renewal of this approved information collection because it is due to expire on August 31, 2016. There are no changes to the existing information collection.

Foreign governments are to petition FSIS for approval to import undenatured inedible egg products into the United States (9 CFR 590.45(d)). Undenatured inedible meat and egg products may be imported into the United States if they meet the requirements of FSIS's regulations (9 CFR 325.11(e) and 590.45(d)). Inedible poultry must be denatured, regardless of the intended use (9 CFR 381.193). Thus, undenatured inedible poultry product may not be imported into the United States.

Firms will complete FSIS Form 9540–4, "Permit Holder—Importation of Undenatured Inedible Product" for the undenatured inedible product that they are importing into the United States. FSIS will use the information on the forms to keep track of the movement of imported undenatured inedible meat and egg products.

FSIS has made the following estimates on the basis of an information collection assessment.

Estimate of Burden: FSIS estimates that it takes respondents an average of 33 hours per year to complete the forms.

Respondents: Importers.

Estimated No. of Respondents: 20.

Estimated No. of Annual Responses per Respondent: 200.

Estimated Total Annual Burden on Respondents: 667 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence, SW., 6065, South Building, Washington, DC 20250; (202) 720–5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, Fax: (202) 690–7442, Email: *program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC on: May 4, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016–10855 Filed 5–6–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2016–0011]

Retail Exemptions Adjusted Dollar Limitations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the dollar limitations on the amount of meat and meat food products, poultry, and poultry products that a retail store can sell to hotels, restaurants, and similar institutions without disqualifying itself for exemption from Federal inspection requirements. In accordance with FSIS's regulations, for calendar year 2016, the dollar limitation for meat and meat food products is being increased from $76,900 to $79,200. The new value for the dollar limitation for poultry and poultry products remains unchanged at $58,200. FSIS is changing the dollar limitations from calendar year 2015 based on price changes for these products evidenced by the Consumer Price Index.

FSIS has provided an 18-month transitional period for mandatory inspection of Siluriformes fish and fish products. FSIS is currently considering the retail dollar limitations for this product. At this time, FSIS will not apply the meat retail dollar limitations to Siluriformes fish and fish products sold at retail because FSIS is assessing retail and similar institutions that produce this product during the 18-month period and because the Consumer Price Index for meat and meat products does not apply to Siluriformes fish and fish products.

DATES: *Effective Date:* June 8, 2016.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Issuances Staff, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6067, South Building, Washington, DC 20250; (202) 690–6510.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) provide a comprehensive statutory framework to ensure that meat, meat food products, poultry, and poultry products prepared for commerce are wholesome, not adulterated, and properly labeled and packaged. Statutory provisions requiring inspection of the preparation or processing of meat, meat food, poultry, and poultry products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants when those operations are conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities (21 U.S.C. 661(c)(2) and 454(c)(2)). FSIS's regulations (9 CFR 303.1(d) and 381.10(d)) elaborate on the conditions under which requirements for inspection do not apply to retail operations involving the preparation of meat and meat food, and processing of poultry and poultry products.

Sales to Hotels, Restaurants, and Similar Institutions

Under these regulations, sales to hotels, restaurants, and similar institutions (other than household consumers) disqualify a retail store for exemption if the product sales exceed either of two maximum limits: 25 percent of the dollar value of total product sales or the calendar year dollar limitation set by the Administrator. The dollar limitation is adjusted automatically during the first quarter of the year if the Consumer Price Index (CPI), published by the Bureau of Labor Statistics, shows an increase or decrease of more than $500 in the price of the same volume of product for the previous year. FSIS publishes a notice of the adjusted dollar limitations in the **Federal Register**. (See 9 CFR 303.1(d)(2)(iii)(b) and 381.10(d)(2)(iii)(b).)

The CPI for 2015 reveals an annual average price increase for meat and meat food products at 3.03 percent and for poultry products at 0.4 percent. When rounded to the nearest $100, the dollar limitation for meat and meat food products increased by $2,327 and the dollar limitation for poultry products increased by $231. In accordance with 9 CFR 303.1(d)(2)(iii)(b) and 381.10(d)(2)(iii)(b), because the dollar limitation of meat and meat food products and poultry products increased by more than $500, FSIS is increasing the dollar limitation on sales to hotels, restaurants, and similar institutions to $79,200 for meat and meat food products. Because the increase in poultry prices is less than $500, FSIS is making no adjustment in dollar limitation for poultry and poultry products. The dollar limitation for poultry and poultry products remains unchanged at $58,200.

Additional Public Notification

FSIS will announce this rule online through the FSIS Web page located at *http://www.fsis.usda.gov/federal-register.*

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/subscribe.*

Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410.

Fax: (202) 690–7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done, at Washington, DC on: May 4, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016–10849 Filed 5–6–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

Office of the Secretary

[DOCKET NO.: 160407316–6316–01]

Public Availability of Department of Commerce FY 2015 Service Contract Inventory

AGENCY: Office of the Secretary, Department of Commerce.

ACTION: Notice of Public Availability of FY 2015 Service Contract Inventories and supplemental data.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the Department of Commerce is publishing this notice to advise the public of the availability of the Fiscal Year (FY) 2015 Service Contract Inventory, a report that analyzes the Department's FY 2014 Service Contract Inventory and an inventory supplement that identifies the amount invoiced and direct labor hours for covered service contract actions.

The service contract inventory provides information on service contract actions over $25,000 made in FY 2015. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance on service contract inventories issued on November 5, 2010, by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP).

ADDRESSES: The Department of Commerce has posted its FY 2015 inventory, summary, FY 2014 Analysis Report and supplemental data on the Office of Acquisition Management homepage at the following link *http://www.osec.doc.gov/oam/.* OFPP's guidance memo on service contract inventories is available at: *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Virna Winters, Director for Acquisitions Policy and Oversight Division at 202–482–4248 or *vwinters@doc.gov.*

Dated: May 3, 2016.

Ellen Herbst,

Chief Financial Officer and Assistant Secretary for Administration.

[FR Doc. 2016–10840 Filed 5–6–16; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–28–2016]

Foreign-Trade Zone (FTZ) 26—Atlanta, Georgia; Notification of Proposed Production Activity; Eastman Kodak Company; Subzone 26N (Aluminum Printing Plates); Columbus, Georgia

Georgia Foreign Trade Zone, Inc., grantee of FTZ 26, submitted a notification of proposed production activity to the FTZ Board on behalf of Eastman Kodak Company (Eastman Kodak), located within Subzone 26N, in Columbus, Georgia. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on April 26, 2016.

The facility is used for the production of aluminum printing plates. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Eastman Kodak from customs duty payments on the foreign-status materials and components used in export production. On its domestic sales, Eastman Kodak would be able to choose the duty rate during customs entry procedures that applies to aluminum printing plates (duty rate 3.7%) for the foreign-status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: ethanaminium; 3H-indolium; benzenediazonium; finished aluminum printing plates; acetic acid; polyvinylphosphonsaure; co polymer-methacrylic acid; propenoic acid; naphthalenesulfonic acid; urethane acrylate polymer; phenolic resin solution; and, aluminum and aluminum alloy coils (duty rates range from 3% to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is June 20, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: May 3, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–10846 Filed 5–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Sanctuary System Business Advisory Council: Public Meeting

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the Sanctuary System Business Advisory Council (council). The meeting is open to the public, and participants may provide comments at the appropriate time during the meeting.

DATES: Members of the public wishing to participate in the meeting must register in advance by Friday, May 20, 2016. The meeting will be held Monday, May, 23, 2016 from 1:30 p.m. to 6:30 p.m. EDT, and an opportunity for public comment will be provided at 5:45 p.m. EDT. These times and the agenda topics described below are subject to change.

ADDRESSES: The meeting will be held at the Florida Keys Eco-Discovery Center, 35 East Quay Road, Key West, Florida 33040. Since the center is closed on Mondays, admittance may be limited to the conference room, except during the time allotted for a scheduled tour. Register by contacting Rebecca Holyoke at 240–533–0685 or *Rebecca.Holyoke@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Rebecca Holyoke, Office of National Marine Sanctuaries, 1305 East West Highway, Silver Spring, Maryland 20910 (Phone: 240–533–0685; Fax: 301–713–0404; Email: *Rebecca.Holyoke@noaa.gov*).

SUPPLEMENTARY INFORMATION: ONMS serves as the trustee for a network of underwater parks encompassing more than 170,000 square miles of marine and Great Lakes waters from Washington state to the Florida Keys, and from Lake Huron to American Samoa. The network includes a system of 13 national marine sanctuaries and Papahānaumokuākea and Rose Atoll marine national monuments. National marine sanctuaries protect our Nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustain healthy environments that are the foundation for thriving communities and stable economies. One of the many ways ONMS ensures public participation in the designation and management of national marine sanctuaries is through the formation of advisory councils. The Sanctuary System Business Advisory Council (council) has been formed to provide advice and recommendations to the Director regarding the relationship of ONMS with the business community. Additional information on the council can be found at *http://sanctuaries.noaa.gov/management/ac/welcome.html.*

Matters to be Considered: The meeting will provide an opportunity for council members to visit a national marine sanctuary, Florida Keys National Marine Sanctuary, for the first time and learn about the site's history, resources, and staff. The council will be introduced to representatives from several of the sanctuary's user groups in order to hear different perspectives on the users and conflicts associated with managing a multi-use area. Additionally, the council will receive a tour of the Florida Keys Eco-Discovery Center that will serve as a point of comparison to discuss current and brainstorm new strategies in which ONMS might maximize visitor engagement everywhere a sanctuary is present. The agenda, available at *http://sanctuaries.noaa.gov/management/bac/meetings.html,* is subject to change.

Authority: 16 U.S.C. Sections 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: April 12, 2016.

John Armor,

Acting Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–10782 Filed 5–6–16; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE560

Marine Mammals; File Nos. 19436 and 19592

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of applications.

SUMMARY: Notice is hereby given that the Aleut Community of St. Paul Island, Tribal Government, Ecosystem Conservation Office [File No. 19436], 2050 Venia Minor Road, P.O. Box 86, St. Paul Island, AK 99660 [Responsible Party: Pamela Lestenkof], and the St. George Traditional Council, Ecosystem Conservation Office [File No. 19592], P.O. Box 940, St. George Island, Alaska 99591 [Responsible Party: Chris Merculief], have applied in due form for a permit to conduct research on and export specimens of northern fur seals (*Callorhinus ursinus*), Steller sea lions (*Eumetopias jubatus*) and harbor seals (*Phoca vitulina*) for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before June 8, 2016.

ADDRESSES: The application and related documents are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting the appropriate File No. from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Rosa L. González or Amy Sloan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicants (File Nos. 19436 and 19592) propose a series of activities to fulfill their Biosampling, Entanglement/Disentanglement, and Island Sentinel Program responsibilities as established under the co-management agreements between NMFS and the Aleut Communities. The activities include ground and aerial surveys (using Unmanned Aircraft Systems); behavioral observations; monitoring; mark-resight; capture for flipper-tagging, standard measurements, and weight; collection of scat, molt, spew, and other samples from the ground; photograph; video; and photo-id of Steller sea lions, northern fur seals, and harbor seals. It also includes incidental harassment of the pinnipeds while performing these activities including remote camera installation, maintenance, and removal. In addition, the applicants would be authorized to collect, salvage, and accept (from subsistence users) samples from dead stranded and subsistence-hunted marine mammals. Unintentional mortality of northern fur seals and Steller sea lions is requested. See tables in the applications for numbers of takes by species, stock and activity. The Aleut Community of St. Paul Island, Tribal Government, Ecosystem Conservation Office activities will be performed in the Pribilof Islands, including St. Paul, St. George, Walrus, and Otter Islands, and Sea Lion Rock, Alaska. The St. George Traditional Council, Ecosystem Conservation Office activities will be performed in St. George Island, Alaska. The permits are requested for 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are consistent with the Preferred Alternative in the Final Programmatic Environmental Impact Statement (PEIS) for Steller Sea Lion and Northern Fur Seal Research (NMFS 2007) and the 2014 Environmental Assessment for Issuance of Permits to take Steller Sea Lions by harassment during surveys using unmanned aerial systems, and that issuance of the permits would not have a significant adverse impact on the human environment.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 4, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–10833 Filed 5–6–16; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

Public Availability of Consumer Product Safety Commission FY 2015 Service Contract Inventory

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission ("CPSC"), in accordance with section 743(c) of Division C of the Consolidated Appropriations Act, 2010 (Pub. L. 111–117, 123 Stat. 3034, 3216), is announcing the availability of CPSC's service contract inventory for fiscal year ("FY") 2015. This inventory provides information on service contract actions that exceeded $25,000 that CPSC made in FY 2015.

FOR FURTHER INFORMATION CONTACT: Eddie Ahmad, Procurement Analyst, Division of Procurement Services, Division of Procurement Services, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814. Telephone: 301–504–7884; email: *aahmad@cpsc.gov.*

SUPPLEMENTARY INFORMATION: On December 16, 2009, the Consolidated Appropriations Act, 2010 (Consolidated Appropriations Act), Public Law 111–117, became law. Section 743(a) of the Consolidated Appropriations Act, titled, "Service Contract Inventory Requirement," requires agencies to submit to the Office of Management and Budget ("OMB"), an annual inventory of service contracts awarded or extended through the exercise of an option on or after April 1, 2010, and describes the contents of the inventory. The contents of the inventory must include:

(A) A description of the services purchased by the executive agency and the role the services played in achieving agency objectives, regardless of whether such a purchase was made through a contract or task order;

(B) The organizational component of the executive agency administering the contract, and the organizational component of the agency whose requirements are being met through contractor performance of the service;

(C) The total dollar amount obligated for services under the contract and the funding source for the contract;

(D) The total dollar amount invoiced for services under the contract;

(E) The contract type and date of award;

(F) The name of the contractor and place of performance;

(G) The number and work location of contractor and subcontractor employees, expressed as full-time equivalents for direct labor, compensated under the contract;

(H) Whether the contract is a personal services contract; and

(I) Whether the contract was awarded on a noncompetitive basis, regardless of date of award.

Section 743(a)(3)(A) through (I) of the Consolidated Appropriations Act. Section 743(c) of the Consolidated Appropriations Act requires agencies to "publish in the **Federal Register** a notice that the inventory is available to the public."

Consequently, through this notice, we are announcing that the CPSC's service contract inventory for FY 2015 is available to the public. The inventory provides information on service contract actions of more than $25,000 that CPSC made in FY 2015. The information is organized by function to show how contracted resources are distributed throughout the CPSC. We developed the inventory in accordance with guidance issued on December 19, 2011 by the OMB. (The OMB guidance is available at: *https://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventory-guidance.pdf*) The CPSC's Division of Procurement Services has posted its inventory (which is identified as "Appendix B"), along with other related materials required by OMB on CPSC's homepage at the following link: *http://www.cpsc.gov/About-CPSC/Agency-Reports/Service-Contract-Inventory/*.

Dated: May 4, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–10805 Filed 5–6–16; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Commission Agenda and Priorities; Notice of Hearing

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of public hearing.

SUMMARY: The U.S. Consumer Product Safety Commission ("Commission") will conduct a public hearing to receive views from all interested parties about the Commission's agenda and priorities for fiscal year 2017, which begins on October 1, 2016, and for fiscal year 2018, which begins on October 1, 2017. We invite members of the public to participate. Written comments and oral presentations concerning the Commission's agenda and priorities for fiscal years 2017 and 2018 will become part of the public record.

DATES: The hearing will begin at 10 a.m. on June 15, 2016, and will conclude the same day. Requests to make oral presentations and the written text of any oral presentations must be received by the Office of the Secretary not later than 5 p.m. Eastern Daylight Time ("EDT") on June 1, 2016.

ADDRESSES: The hearing will be in the Hearing Room, 4th Floor of the Bethesda Towers Building, 4330 East West Highway, Bethesda, MD 20814. Requests to make oral presentations, (along with the texts of oral presentations) and written comments should be captioned, "Agenda and Priorities FY 2017 and/or 2018," and sent by electronic mail (email) to: *cpsc-os@cpsc.gov,* or mailed or delivered to the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814. Requests and comments must be received no later than 5 p.m. EDT on June 1, 2016.

FOR FURTHER INFORMATION CONTACT: For information about the hearing, or to request an opportunity to make an oral presentation, please send an email, call, or write Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; email: *cpsc-os@cpsc.gov;* telephone: (301) 504–7923; facsimile: (301) 504–0127. An electronic copy of the CPSC's budget request for fiscal year 2017 can be found at: *www.cpsc.gov/performance-and-budget.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(j) of the Consumer Product Safety Act ("CPSA") (15 U.S.C. 2053(j)) requires the Commission to establish an agenda for action under the laws the Commission administers, and to the extent feasible, select priorities for action at least 30 days before the beginning of each fiscal year. Section 4(j) of the CPSA provides further that before establishing its agenda and priorities, the Commission conduct a public hearing and provide an opportunity for the submission of comments.

The Commission is in the process of preparing the agency's fiscal year 2017 Operating Plan and fiscal year 2018 Congressional Budget Request. Fiscal year 2017 begins on October 1, 2016, and fiscal year 2018 begins on October 1, 2017. The Commission's priorities for fiscal years 2017 and 2018 will align with the CPSC's 2016—2020 Strategic Plan, which was released for public comment in February 2016. Through this notice, the Commission invites the public to comment on the following questions:

1. What are the priorities the Commission should consider emphasizing and dedicating resources toward in the fiscal year 2017 Operating Plan and/or the fiscal year 2018 Congressional Budget Request?

2. What activities should the Commission consider deemphasizing in the fiscal year 2017 Operating Plan and/or the fiscal year 2018 Congressional Budget Request?

3. Should the Commission consider making any changes or adjustments to the agency's proposed or ongoing education, safety standards activities, regulation, and enforcement efforts in fiscal years 2017 and/or 2018, keeping in mind the CPSC's existing policy on establishing priorities for Commission action (16 CFR 1009.8)? The CPSC's budget request for fiscal year 2017 can be found at: *www.cpsc.gov/performance-and-budget.* Comments are welcome on whether particular action items should be higher priority than others, should not be included, or should be added to the fiscal year 2017 and/or fiscal year 2018 agendas.

4. Which candidates should the Commission consider for retrospective review of existing rules for fiscal year

2017 and/or 2018 agendas? This is intended to facilitate the identification of rules that warrant repeal or modification, including rules that would benefit from strengthening, complementing, or modernizing. Consistent with Executive Orders ("E.O.") 13579, 13563, and 13610 and the Regulatory Flexibility Act ("RFA"), the CPSC systematically reviews its regulations to ensure consistency among all regulations in accomplishing program goals. The CPSC's latest Semiannual Regulatory Agenda, which was issued in December 2015, can be found at: *www.federalregister.gov/articles/2015/12/15/2015-30672/semiannual-regulatory-agenda.*

II. Requests To Make Presentations or Submit Written Comments

Persons who desire to make oral presentations at the hearing on June 15, 2016 should submit their request, including the text of their oral presentation, by email to: *cpsc-os@cpsc.gov,* or by mail or delivery to the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7923; facsimile (301) 504–0127. Requests to make oral presentations and texts of the presentation must be received no later than 5 p.m. EDT on June 1, 2016. Presentations should be limited to approximately 10 minutes. The Commission reserves the right to impose further time limitations on all presentations and further restrictions to avoid duplication of presentations.

If you do not want to make an oral presentation, but would like to provide written comments, you may do so. Please submit written comments in the manner described in the previous paragraph. Written comments must be received no later than 5 p.m. EDT on June 1, 2016.

Dated: May 4, 2016.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2016–10804 Filed 5–6–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Ocean Research Advisory Panel

AGENCY: Department of the Navy, DoD.

ACTION: Notice of open meeting.

SUMMARY: The Ocean Research Advisory Panel (ORAP) will hold a regularly scheduled meeting. The meeting will be open to the public.

DATES: The meeting will be held on Tuesday, May 31, 2016, from 1:00 p.m. to 5:00 p.m. and on Wednesday, June 1, 2016, from 9:00 a.m. to 3:00 p.m. Members of the public should submit their comments in advance of the meeting to the meeting Point of Contact.

ADDRESSES: The meeting will be held at 4100 Fairfax Drive, Suite 800, Arlington, VA, 22203.

FOR FURTHER INFORMATION CONTACT: CDR Joel W. Feldmeier, Office of Naval Research, 875 North Randolph Street, Suite 1425, Arlington, VA 22203–1995, telephone 706–696–5121.

SUPPLEMENTARY INFORMATION: This notice of open meeting is provided in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2). The meeting will include discussions on ocean research, resource management, and other current issues in the ocean science and management communities.

Dated: May 3, 2016.

N.A. Hagerty-Ford,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2016–10857 Filed 5–6–16; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Quadrennial Energy Review: Notice of Public Meetings

AGENCY: Office of Energy Policy and Systems Analysis, Secretariat, Quadrennial Energy Review Task Force, Department of Energy.

ACTION: Notice of public meetings and updating meeting start time.

SUMMARY: At the direction of the President, the U.S. Department of Energy (DOE or Department), as the Secretariat for the Quadrennial Energy Review Task Force (QER Task Force), will convene public meetings for the second installment of the Quadrennial Energy Review, an integrated study of the U.S. electricity system from generation through end use. A mixture of panel discussions and a public comment period will frame multi-stakeholder discourse around deliberative analytical questions relating to the intersection of electricity and its role in promoting economic competitiveness, energy security, and environmental responsibility.

DATES: See the **SUPPLEMENTARY INFORMATION** section for meeting dates and locations.

ADDRESSES: Between February 4, 2016 and July 1, 2016, you may submit written comments online at *http://energy.gov/qer* or by U.S. mail to the Office of Energy Policy and Systems Analysis, EPSA–60, QER Meeting Comments, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0121.

FOR FURTHER INFORMATION CONTACT: John Richards, EPSA–60, U.S. Department of Energy, Office of Energy Policy and Systems Analysis, 1000 Independence Avenue SW., Washington, DC 20585–0121. *Telephone:* 202–586–0507 *Email: John.Richards@Hq.Doe.Gov.*

SUPPLEMENTARY INFORMATION: On January 9, 2014, President Obama issued a *Presidential Memorandum —Establishing a Quadrennial Energy Review.* To accomplish this review, the Presidential Memorandum establishes a Quadrennial Energy Review Task Force to be co-chaired by the Director of the Office of Science and Technology Policy, and the Director of the Domestic Policy Council. Under the Presidential Memorandum, the Secretary of Energy shall provide support to the Task Force, including support for coordination activities related to the preparation of the Quadrennial Energy Review (QER) Report, policy analysis and modeling, and stakeholder engagement.

The Quadrennial Energy Review process itself involves robust engagement of federal agencies and outside stakeholders, and further enables the federal government to translate policy goals into a set of analytically based, integrated actions for proposed investments over a four year planning horizon. Unlike traditional federal Quadrennial Review processes, the QER is conducted in a multi-year installment series to allow for more focused analysis on particular sub-sectors of the energy system. The initial focus for the Quadrennial Energy Review was our Nation's transmission, storage and distribution infrastructures that link energy supplies to intermediate and end users, because these capital-intensive infrastructures tend to set supply and end use patterns, investments and practices in place for decades. On April 21, 2015, the Quadrennial Energy Review Task Force released its first Quadrennial Energy Review installment report entitled, "Energy Transmission, Storage, and Distribution Infrastructure". Among the issues highlighted by the analysis in the first installment of the QER were the growing dependencies of all critical infrastructures and economic sectors on electricity, as well as, the increasing interdependence of the various energy subsectors. In response to these findings, and to provide an appropriate consideration of an energy sector undergoing significant technological and regulatory change, the second installment of the QER will conduct a comprehensive review of the nation's electricity system, from generation to end use, including a more comprehensive look at electricity transmission, storage, and distribution infrastructure covered in installment one. The electricity system encompasses not just physical structures, but also a range of actors and institutions. Under this broad framing, the second installment intends to consider the roles and activities of all relevant actors, industries, and institutions integral to continuing to supply reliable and affordable electricity at a time of dramatic change in technology development. Issues to be considered in QER analyses include fuel choices, distributed and centralized generation, physical and cyber vulnerabilities, federal, state, and local policy direction, expectations of residential and commercial consumers, and a review of existing and evolving business models for a range of entities throughout the system.

Significant changes will be required to meet the transformational opportunities and challenges posed by our evolving electricity system. The Administration is seeking public input on key questions relating to possible federal actions that would address the challenges and take full advantage of the opportunities of this changing system to meet the Nation's objectives of reliable, affordable and clean electricity. Over the course of 2016, the Secretariat for the Quadrennial Energy Review Task Force will hold a series of public meetings to discuss and receive comments on the issues outlined above, and well as, others, as they relate to the second installment of the Quadrennial Energy Review.

The Department of Energy has a broad role in energy policy development and the largest role in implementing the Federal Government's energy research and development portfolio. Many other executive departments and agencies also play key roles in developing and implementing policies governing energy resources and consumption, as well as, associated environmental impacts. In addition, non-Federal actors are crucial contributors to energy policies. Because most energy and related infrastructure is owned by private entities, investment by and engagement of, input from the private sector is necessary to develop and implement effective policies. State and local policies, the views of non-governmental, environmental, faith-based, labor, and other social organizations, and contributions from the academic and non-profit sectors are also critical to the development and implementation of effective Federal energy policies.

The interagency Quadrennial Energy Review Task Force, which includes members from all relevant executive departments and agencies, will develop an integrated review of energy policy that integrates all of these perspectives. It will build on the foundation provided in the Administration's *Blueprint for a Secure Energy Future* of March 30, 2011, and *Climate Action Plan* released on June 25, 2013. The Task Force will offer recommendations on what additional actions it believes would be appropriate. These may include recommendations on additional executive or legislative actions to address the energy challenges and opportunities facing the Nation.

Quadrennial Energy Review Public Meetings

The public meetings will be held on:

- May 9, 8:30 a.m., at the University of Texas, Peter O' Donnell, Jr. Applied Computational Engineering and Sciences Building, Avaya Auditorium (POB 2.302), 201 E. 24th Street, Austin Texas.
- May 10, 9:30 a.m., at City Hall, Tom Bradley Tower Room, 200 N. Spring St., Los Angeles, California.
- May 24, 10:00 a.m., at Georgia Tech GTRI Conference Center, 250 14th Street NW., Atlanta, Georgia.

Each meeting will feature facilitated panel discussions, followed by an open microphone session. People who would like to speak during the open microphone session at the public meeting should come prepared to speak for no more than five minutes and will be accommodated on a first-come, first-served basis, according to the order in which they register to speak on a sign-in sheet available at the meeting location, on the morning of the meeting. In advance of the meetings, DOE anticipates making publicly available a briefing memorandum providing useful background information regarding the topics under discussion at the meeting. DOE will post this memorandum on its Web site: *http://energy.gov/qer.*

Submitting comments online. DOE will accept public comments on the QER from February 4, 2016, to July 1, 2016, at *energy.gov/qer.* Submitting comments online to the DOE Web site will require you to provide your name and contact information. Your contact information will be viewable to DOE staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). Your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through the DOE Web site cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section, below.

If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked "confidential" including all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination. Confidential information should be submitted to the Confidential QER email address: *QERConfidential@hq.doe.gov.*

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest. It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

Issued in Washington, DC, on May 4, 2016.

April Salas,

QER Secretariat Director, Quadrennial Energy Review Task Force, U.S. Department of Energy.

[FR Doc. 2016–10874 Filed 5–6–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Public Availability of Department of Energy FY 2015 Service Contract Inventory

AGENCY: Department of Energy.

ACTION: Notice of public availability of FY 2015 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the Department of Energy (DOE) is publishing this notice to advise the public on the availability of the FY 2015 Service Contract inventory. This inventory provides information on service contract actions over $25,000 that DOE completed in FY 2015. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010, by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* On December 19, 2011, OFPP issued additional guidance available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventory-guidance.pdf.*

Except for minor changes to reporting deadlines, the guidance for preparing and analyzing FY 2015 inventories is essentially unchanged from OFPP's November 5, 2010, guidance for preparing the FY 2010 inventory. DOE has posted its inventory and a summary of the inventory at: *http://energy.gov/management/downloads/service-contract-inventory.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Jeff Davis in the Strategic Programs Division at 202–287–1877 or *jeff.davis@hq.doe.gov.*

Dated: April 28, 2016.

David Leotta,

Director, Office of Contract Management.

[FR Doc. 2016–10801 Filed 5–6–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–64–000]

Notice of Complaint

Belmont Municipal Light Department; Braintree Electric Light Department; Concord Municipal Light Plant; Georgetown Municipal Light Department; Groveland Electric Light Department; Hingham Municipal Lighting Plant; Littleton Electric Light & Water Department; Middleborough Gas & Electric Department; Middleton Electric Light Department; Reading Municipal Light Department; Rowley Municipal Lighting Plant; Taunton Municipal Lighting Plant; Wellesley Municipal Light Plant, v. Central Maine Power Company; Emera Maine (formerly known as Bangor Hydro-Electric Company); Eversource Energy Service Company and its operating company affiliates: The Connecticut Light and Power Company, Western Massachusetts Electric Company, Public Service Company of New Hampshire, and NSTAR Electric Company; New England Power Company d/b/a National Grid; New Hampshire Transmission LLC d/b/a NextEra; The United Illuminating Company; Fitchburg Gas and Electric Light Company; and Vermont Transco, LLC

Take notice that on April 26, 2016, pursuant to sections 206 and 306 of the Federal Power Act[1] and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[2] Belmont Municipal Light Department; Braintree Electric Light Department; Concord Municipal Light Plant; Georgetown Municipal Light Department; Groveland Electric Light Department; Hingham Municipal Lighting Plant; Littleton Electric Light & Water Department; Middleborough Gas & Electric Department; Middleton Electric Light Department; Reading Municipal Light Department; Rowley Municipal Lighting Plant; Taunton Municipal Lighting Plant; Wellesley Municipal Light Plant (Complainants), filed a formal complaint against Central Maine Power Company; Emera Maine (formerly known as Bangor Hydro-Electric Company); Eversource Energy Service Company and its operating company affiliates: The Connecticut Light and Power Company, Western Massachusetts Electric Company, Public Service Company of New Hampshire, and NSTAR Electric Company; New England Power Company; New Hampshire Transmission LLC; The United Illuminating Company; Fitchburg Gas and Electric Light Company; and Vermont Transco, LLC (Respondents). The Complainants are alleging that the current 10.57 percent return on equity used in calculating formula rates for transmission service under the ISO New England, Inc. Open Access Transmission Tariff is excessive and should be reduced, as more fully explained in the complaint.

Complainants certify that copies of the Complaint were served on contacts for Respondents.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

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[1] 16 U.S.C. 791a–828c, 824e, and 825e.

[2] 18 CFR 385.206.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 16, 2016.

Dated: May 3, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10786 Filed 5–6–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–112–000.
Applicants: West Valley Power, LLC.
Description: Application of West Valley Power, LLC for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action.
Filed Date: 4/29/16.
Accession Number: 20160429–5536.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: EC16–113–000.
Applicants: PacifiCorp.
Description: Application of PacifiCorp for Approval of Acquisition of under Jurisdictional Assets pursuant to Section 203 of Federal Power Act.
Filed Date: 4/29/16.
Accession Number: 20160429–5546.
Comments Due: 5 p.m. ET 5/20/16.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–89–000.
Applicants: Elevation Solar C LLC.
Description: Self-Certification of Exempt Wholesale Generator Status of Elevation Solar C LLC.
Filed Date: 4/28/16.
Accession Number: 20160428–5454.
Comments Due: 5 p.m. ET 5/19/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1549–000.
Applicants: Pacific Gas and Electric Company.
Description: Section 205(d) Rate Filing: Quarterly Filing of City and County of San Francisco's WDT SA 275 for Q1 2016 to be effective 3/31/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5468.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1550–000.
Applicants: Southwest Power Pool, Inc.
Description: Section 205(d) Rate Filing: 3060 SWEPCO and Tex-La Electric Interconnection Agreement to be effective 4/20/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5106.
Comments Due: 5 p.m. ET 5/23/16

Docket Numbers: ER16–1551–000.
Applicants: Southwest Power Pool, Inc.
Description: Section 205(d) Rate Filing: 2142R2 Golden Spread Electric Cooperative, Inc. NITSA NOA to be effective 4/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5107.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1552–000.
Applicants: Ameren Illinois Company, Midcontinent Independent System Operator, Inc.
Description: Section 205(d) Rate Filing: 2016–05–02_SA 2917 Ameren Illinois-Prairie Power CA (Yantisville) to be effective 4/5/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5111.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1553–000.
Applicants: Atlantic City Electric Company.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5140.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1554–000.
Applicants: AV Solar Ranch 1, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5141.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1555–000.
Applicants: Baltimore Gas and Electric Company.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5142.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1556–000.
Applicants: Beebe 1B Renewable Energy, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5143.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1557–000.
Applicants: Beebe Renewable Energy, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5144.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1558–000.
Applicants: Bethlehem Renewable Energy, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5145.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1559–000.
Applicants: Calvert Cliffs Nuclear Power Plant, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5146.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1560–000.
Applicants: Cassia Gulch Wind Park, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5147.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1561–000.
Applicants: Continuum Retail Energy Services, L.L.C.
Description: Notice of Cancellation of Market-Based Rate Tariff of Continuum Retail Energy Services, L.L.C.
Filed Date: 4/29/16.
Accession Number: 20160429–5540.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1562–000.
Applicants: CER Generation, LLC.
Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5148.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1563–000.

Applicants: Commonwealth Edison Company.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5149.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1564–000.

Applicants: The AES Corporation.

Description: Election for Review and Authorization of The AES Corporation pursuant to Section 1275 of the Energy Policy Act of 2015.

Filed Date: 4/29/16.

Accession Number: 20160429–5541.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1565–000.

Applicants: Constellation Energy Commodities Group Maine, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5151.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1566–000.

Applicants: Constellation Energy Services, Inc.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5152.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1567–000.

Applicants: Constellation Energy Services of New York.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5153.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1568–000.

Applicants: Constellation Mystic Power, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5157.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1569–000.

Applicants: Constellation NewEnergy, Inc.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5159.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1570–000.

Applicants: Constellation Power Source Generation, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5160.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1571–000.

Applicants: Cow Branch Wind Power, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5162.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1572–000.

Applicants: CR Clearing, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5164.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1573–000.

Description: Notice of Cancellation market-based rate tariff of California Clean Power Corp.

Filed Date: 4/29/16.

Accession Number: 20160429–5545.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1574–000.

Applicants: Criterion Power Partners, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5167.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1575–000.

Applicants: Eastern Landfill Gas, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5170.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1576–000.

Applicants: Exelon Framingham, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5172.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1577–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Section 205(d) Rate Filing: 2016–05–02 Emergency Pricing True-Up to be effective 7/1/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5173.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1578–000.

Applicants: Delmarva Power & Light Company.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5175.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1579–000.

Applicants: Exelon Generation Company, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5176.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1580–000.

Applicants: Potomac Electric Power Company.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5177.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1581–000.

Applicants: Exelon New Boston, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5178.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1582–000.

Applicants: Exelon West Medway, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5179.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1583–000.

Applicants: Exelon Wind 4, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5180.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1584–000.

Applicants: Exelon Wyman, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5198.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1585–000.

Applicants: Fair Wind Power Partners, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5182.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1586–000.

Applicants: Fourmile Wind Energy, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5199.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1587–000.

Applicants: Handsome Lake Energy, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5201.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1588–000.

Applicants: Harvest II Windfarm, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5202.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1589–000.

Applicants: Harvest Windfarm, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5203.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1590–000.

Applicants: High Mesa Energy, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5206.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1591–000.

Applicants: Michigan Wind 1, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5207.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1592–000.

Applicants: Michigan Wind 2, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5209.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1593–000.

Applicants: Public Service Company of Colorado.

Description: Section 205(d) Rate Filing: PSCo–TSGT–WAPA Concur Montrose Sub 438 to be effective 7/2/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5211.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1594–000.

Applicants: Nine Mile Point Nuclear Station, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5212.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1595–000.

Applicants: PECO Energy Company.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5215.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1596–000.

Applicants: Pepco Energy Services, Inc.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5221.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1597–000.

Applicants: R.E. Ginna Nuclear Power Plant, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5229.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1598–000.

Applicants: Shooting Star Wind Project, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5230.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1599–000.

Applicants: Tuana Springs Energy, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5232.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1600–000.

Applicants: Southwest Power Pool, Inc.

Description: Section 205(d) Rate Filing: 3189 Basin Electric and Northern States Power Attachment AO to be effective 4/1/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5234.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1601–000.

Applicants: Wildcat Wind, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5239.

Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1602–000.

Applicants: Wind Capital Holdings, LLC.

Description: Compliance filing: Exelon MBR Entities Omnibus Tariff Updates to be effective 5/3/2016.

Filed Date: 5/2/16.

Accession Number: 20160502–5241.

Comments Due: 5 p.m. ET 5/23/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–30–000.

Applicants: El Paso Electric Company.

Description: Application for Renewal of Section 204 Authorization of El Paso Electric Company.

Filed Date: 4/29/16.

Accession Number: 20160429–5538.

Comments Due: 5 p.m. ET 5/20/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10767 Filed 5–6–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR16–13–000]

Saddlehorn Pipeline Company, LLC; Notice of Amended Petition for Declaratory Order

Take notice that on April 29, 2016, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2015), Saddlehorn Pipeline Company, LLC ("Saddlehorn"), filed an amended petition for a declaratory order concerning clarifying language to its rules and regulations tariff governing line fill, to accommodate the restructuring of the original Saddlehorn project into an undivided joint interest pipeline with Grand Mesa Pipeline, LLC, all as more fully explained in the petition, as amended.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on May 11, 2016.

Dated: May 3, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10787 Filed 5–6–16; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP15–554–000; CP15–554–001]

Atlantic Coast Pipeline, LLC; Supplemental Notice of Intent To Prepare an Environmental Impact Statement and Proposed Land and Resource Plan Amendment(s) for the Proposed Atlantic Coast Pipeline, Request for Comments on Environmental Issues Related to New Route and Facility Modifications, and Notice of Public Scoping Meetings

On February 27, 2015, the Federal Energy Regulatory Commission (FERC or Commission) issued in Docket Nos. PF15–5–000 and PF15–6–000 a *Notice of Intent to Prepare an Environmental Impact Statement for the Planned Supply Header Project and Atlantic Coast Pipeline Project, and Request for Comments on Environmental Issues, and Notice of Public Scoping Meetings* (NOI). On September 18, 2015, Atlantic Coast Pipeline, LLC (Atlantic) and Dominion Transmission, Inc. (DTI) filed applications with the FERC in Docket Nos. CP15–554–000 and CP15–555–000 pursuant to sections 7(b) and 7(c) of the Natural Gas Act (NGA) and Parts 157 and 284 of the Commission's regulations. Atlantic and DTI are seeking Certificates of Public Convenience and Necessity (Certificates) to construct, own, and operate a natural gas pipeline and related facilities. On March 1, 2016, Atlantic filed an amendment to its application to incorporate route and facility modifications in West Virginia, Virginia, and North Carolina. This Supplemental Notice is being issued to seek comments on the new pipeline route and facility modifications and opens a new scoping period for interested parties to file comments on environmental issues specific to these modifications.

Information about the facilities proposed by Atlantic and DTI can be found on our public dockets referenced above and on each applicant's Web site at *www.dom.com/corporate/what-we-do/atlantic-coast-pipeline* or *www.dom.com/corporate/what-we-do/natural-gas/supply-header-project.* The FERC's environmental impact statement (EIS) will encompass all proposed facilities and be used by the Commission in its decision-making process to determine whether the Atlantic Coast Pipeline (ACP) and Supply Header Project are in the public convenience and necessity.

The FERC will be the lead federal agency for the preparation of the EIS. The U.S. Forest Service (USFS) is participating as a cooperating agency because the ACP would cross the Monongahela National Forest (MNF) and the George Washington National Forest (GWNF) in West Virginia and Virginia. As a cooperating agency, the USFS intends to adopt the EIS per Title 40 of the Code of Federal Regulations, Part 1506.3 to meet its responsibilities under the National Environmental Policy Act (NEPA) regarding Atlantic's application for a Right-of-Way Grant and Temporary Use Permit for crossing federally administered lands. In addition, there may be a need for the USFS to amend the MNF and GWNF Land and Resource Management Plans (LRMP) to allow for the ACP to be constructed on USFS lands. The EIS will also provide the documentation to support needed amendments to the LRMPs. Additional details on the USFS' LRMP Amendment Process is provided on page 8.

The Commission previously solicited public input on the ACP in the spring of 2015. We[1] are specifically seeking comments on the new pipeline route and facility modifications to help the Commission staff determine what issues need to be evaluated in the EIS. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts from the new route and proposed modifications. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before June 2, 2016. If you have previously provided comments on the ACP or Supply Header Projects, you do not need to resubmit them.

You may submit comments in written form or verbally. In lieu of or in addition to sending written comments, the Commission invites you to attend the public scoping meetings scheduled as follows:

Date and time	Location
Friday, May 20, 2016, 10:00 a.m.–7:00 p.m.	Marlinton Community Wellness Center, 320 9th Street, Marlinton, WV 24954.
Saturday, May 21, 2016, 10:00 a.m.–7:00 p.m.	Bath County High School, 464 Charger Lane, Hot Springs, VA 24445.

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[1] "We," "us," and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

The purpose of these scoping meetings is to provide an opportunity to verbally comment on the project modifications. You may attend *at any time* during the meeting, as the primary goal of a scoping meeting is for us to hear and document your environmental concerns. There will not be a formal presentation by Commission staff; however, we will be available to answer your questions about the FERC environmental review process. Representatives of Atlantic will also be present to answer questions about the project.

Verbal comments will be recorded by a court reporter and transcripts will be placed into the docket for the project and made available for public viewing on FERC's eLibrary system (see page 12 "Additional Information" for instructions on using eLibrary). It is important to note that verbal comments hold the same weight as written or electronically submitted comments. If a significant number of people are interested in providing verbal comments, a time limit of 3 to 5 minutes may be implemented for each commenter to ensure all those wishing to comment have the opportunity to do so within the designated meeting time. Time limits will be strictly enforced if they are implemented.

This Supplemental Notice is being sent to the Commission's current environmental mailing list for this project, including those landowners that are newly affected by the proposed pipeline route modifications. State and local government representatives are asked to notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a newly affected landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if the easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility on My Land? What Do I Need To Know?" is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Summary of Project Modifications

In its amended application, Atlantic proposes a major route change through the MNF and GWNF that would affect landowners in Randolph and Pocahontas Counties, West Virginia and Highland, Bath, and Augusta Counties, Virginia. Other, smaller route changes proposed in the amendment would affect landowners in Nelson and Dinwiddie Counties, Virginia; and Cumberland and Johnston Counties, North Carolina. The amended facilities would increase the total length of the pipeline from about 556 miles to 599.7 miles and compressor station horsepower from 40,715 horsepower to 53,515 horsepower at the proposed Buckingham County, Virginia compressor station, all as more fully described in the amended application. An overview map of the proposed ACP and SHP and illustrations of these alternatives are provided in Appendix 1. Detailed alternative route location information can be found on DTI's interactive web mapping application at *https://www.dom.com/corporate/what-we-do/atlantic-coast-pipeline.*

GWNF 6 Route Modification (Randolph and Pocahontas Counties, West Virginia; Highland, Bath, and Augusta Counties, Virginia)

To reduce potential impacts on the Cheat Mountain salamander, West Virginia Northern flying squirrel, and Cow Knob salamander, and to avoid sensitive habitats and land uses, Atlantic incorporated the GWNF 6 Alternative into its proposed pipeline route between AP–1 mileposts (MPs) 47.5 and 115.2. Relative to Atlantic's originally proposed route, the GWNF 6 Route Modification initially heads south approximately 13 miles, passing east of Hicks Ridge and west of Kumbrabow State Forest. The route continues south/southeast approximately 13 miles, crossing Point Mountain and passing east of Elk Mountain and Mingo Knob. The route enters Pocahontas County, West Virginia southeast of Mingo Knob at Valley Mountain, and continues south approximately 8 miles, crossing Mace, Tallow, and Gibson Knobs, passing west of the Snowshoe Ski Resort. South of Gibson Knob, the route heads southeast approximately 17 miles, passing south of Cheat Mountain and Back Allegheny Mountain; crossing Cloverlick Mountain, Seneca State Forest, and Michael Mountain; and entering Highland County, Virginia just west of Big Crooked Ridge.

After entering Virginia, the GWNF 6 Alternative continues east approximately 3 miles then southeast approximately 8 miles, crossing Little Ridge, Big Ridge, and Little Mountain and passing east of Piney Ridge. The route enters Bath County, Virginia near U.S. Highway 220, and continues southeast approximately 14 miles, crossing Back Creek Mountain, Jack Mountain, and Tower Hill Mountain and passing south of Shenandoah Mountain at South Sister Knob. The route heads northeast approximately 20 miles, passing north of Chestnut Ridge; entering Augusta County, Virginia near Brushy Ridge; and crossing Deerfield Valley on the east side of Shenandoah Mountain. The GWNF 6 Alternative intersects Atlantic's filed route near MP 115.2 at Broad Draft near West Augusta, Virginia.

In addition to the route modification described above, Atlantic also proposes to increase the horsepower of its proposed Compressor Station 2 in Buckingham County, Virginia and install eight additional valve sites.

Snowshoe Route Adjustment (Randolph and Pocahontas Counties, Virginia)

Atlantic incorporated the Snowshoe Route Variation into its proposed route between AP–1 MPs 66.7 and 70.1 to avoid modeled habitat for the Cheat Mountain salamander and the Cheat Mountain Civil War Battlefield, as well as reducing the amount of forest land and other sensitive environmental features crossed. Relative to Atlantic's originally proposed route, the Snowshoe Route Variation initially heads west/southwest for 0.8 mile, crossing the main ridge on Valley Mountain, then continuing for approximately 2.6 miles, descending Valley Mountain, crossing Dry Fork Spring and Middle Mountain, and entering the valley along Big Fork Spring. The route then crosses Highway 56 in the valley, and continues to the south/southwest for approximately 1.3 miles, ascending Tallow Knob and reconnecting to the originally proposed route at MP 70.1.

Singleton Route Adjustment (Bath County, Virginia)

Atlantic incorporated the Singleton Route Adjustment into its proposed route between AP–1 MPs 91.9 and 92.7 to avoid an open-space conservation easement held by the Virginia Outdoors Foundation. Relative to Atlantic's originally proposed route, the Singleton Route Adjustment is generally parallel to and within 0.3 mile of the corresponding segment of the originally proposed route.

Horizons Village 2 Route Adjustment (Nelson County, Virginia)

In response to our environmental information request dated December 4, 2015, and to avoid crossing the Spruce Creek Tributary Conservation Site, Atlantic incorporated the Horizons Village 2 Route Adjustment into its proposed pipeline route between AP–1 MPs 162.0 and 162.8. Relative to Atlantic's originally proposed route, the Horizons Village 2 Route Adjustment would pass approximately 310 feet south of the conservation site.

Highway 29 Route Adjustment (Nelson County, Virginia)

In response to our environmental information request dated December 4, 2015, and to avoid an area of high slip potential, improve the location for the crossing of Highway 29, and optimize the amount of agricultural and open land crossed, Atlantic incorporated the Highway 29 Route Variation into its proposed pipeline route between AP–1 MPs 167.0 and 171.1. Relative to Atlantic's originally proposed route, the Highway 29 Route Variation initially heads south for approximately 0.2 mile following a ridge to the top of Roberts Mountain, then continues southeast for approximately 1.7 miles following a ridge to the base of Roberts Mountain at the crossing of Davis Creek. This segment of the route crosses Highway 29 on the same north trending finger ridge as the proposed route, but in an area with flatter terrain at the crossing. On the south side of the highway, the route continues to the southeast for approximately 2.2 miles, including a 0.2-mile-long segment parallel to Starvale Lane. The Highway 29 Route Variation reconnects to the originally proposed route on the east side of Wheelers Cove Road at approximately MP 171.1.

Beaver Pond Creek Route Adjustment (Dinwiddie County, Virginia)

In response to our environmental information request dated December 4, 2015, and to reduce the number of crossings of Beaver Pond Creek and address comments provided by the Ward Burton Wildlife Foundation, Atlantic incorporated the Beaver Pond Creek Route Variation into its proposed pipeline route between AP–1 MPs 256.5 and 259.3. Relative to Atlantic's originally proposed route, the Beaver Pond Creek Route Variation initially heads south/southwest for approximately 111.1 miles to a point just south of Whitmore Road, then heads south for approximately 1.6 miles over mostly upland terrain, crossing Beaver Creek Pond in one location, reconnecting with the originally proposed route near MP 259.3.

Juniper Farms Route Adjustment (Johnston County, North Carolina)

Atlantic incorporated the Juniper Farms Route Variation into its proposed route between AP–2 MPs 96.9 and 98.4 to avoid a wetland mitigation bank, and to reduce the amount of sensitive environmental features and constraints crossed. Relative to Atlantic's originally proposed route, the Juniper Farms Route Variation initially heads southwest for approximately 1.2 miles, passing east of the eastern boundary of the mitigation bank. The route variation then reconnects with the originally proposed route at MP 98.4 on the north side of the Neuse River crossing.

Fayetteville Major Route Modification (Cumberland County, North Carolina)

In response to our environmental information request dated December 4, 2015, and to increase collocation with an existing Progress Energy Carolinas (PEC) 500 kilovolt electric transmission line, and reduce the number of affected property owners, the number of waterbody crossings, and temporary wetland impacts, Atlantic incorporated the Fayetteville Major Route Alternative into its proposed pipeline route between AP–2 MPs 133.1 and 157.5. Relative to Atlantic's originally proposed route, the Fayetteville Major Route Alternative initially heads south/southeast for approximately 3.9 miles to the point where it intersects the existing PEC electric transmission line, crossing Drum Road, Interstate 95, and Goldsboro Road. The route then heads south for approximately 16.7 miles, parallel to and adjacent to the electric transmission line corridor, and crosses Clinton Road and Cedar Creek Road. The route continues west for approximately 5.5 miles, crossing Tabor Church Road, Cape Fear River, and North Carolina State Highway 87 reconnecting with the originally proposed route near MP 157.5.

The EIS Process

NEPA requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EIS. We will consider all filed comments during the preparation of the EIS.

In the EIS we will discuss impacts that could occur as a result of the construction and operation of the proposed projects under these general headings:

☐ Geology and soils;
☐ land use;
☐ water resources, fisheries, and wetlands;
☐ cultural resources;
☐ vegetation and wildlife;
☐ air quality and noise;
☐ endangered and threatened species;
☐ outdoor recreation and scenery
☐ socioeconomics; and
☐ public safety.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EIS will present our independent analysis of the issues. We will publish and distribute the draft EIS for public comment. After the comment period, we will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 9.

The U.S. Army Corps of Engineers (USACE) and USFS also have responsibilities under NEPA and can adopt the EIS for their own agencies purposes. The USFS intends to use this EIS to evaluate the effects of the ACP on lands and facilities managed by the agency and to address any proposed amendments of applicable LRMPs that would be necessary to make provisions for the projects.

With this Supplemental Notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to these projects to formally cooperate with us in the preparation of the EIS.[2] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. As discussed above, the USFS has expressed its intention to participate as a cooperating agency in the preparation of the EIS to satisfy its NEPA responsibilities related to these projects. In addition to the USFS, the USACE, U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service Great Dismal Swamp National Wildlife Refuge, West Virginia Department of Environmental Protection, and West Virginia Division of Natural Resources have also agreed to participate as cooperating agencies.

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[2] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

Proposed Actions of the U.S. Forest Service

On November 12, 2015 Atlantic submitted a right-of-way grant application to the USFS to construct, operate, maintain, and eventually decommission a natural gas pipeline that crosses lands and facilities administered by the USFS. In addition, there is a need for the USFS to consider amending affected LRMPs to make provision for the ACP right-of-way.

The proposed action before the USFS has two components. First, in accordance with the Minerals Leasing Act, the USFS would issue a right-of-way grant in response to ACP's application for the project to occupy federal lands. The USFS may submit specific stipulations, including mitigation measures, for inclusion in the right-of-way grant related to lands, facilities, and easements within its jurisdiction. Second, the USFS may need to amend its LRMPs for the Monongahela and George Washington National Forests if analysis shows that construction of the ACP would not be consistent with the LRMP standards or other plan components. In addition, the ACP, as proposed, does not follow a designated utility corridor through the GWNF. If the proposed route were authorized with the right-of-way grant, the GWNF LRMP would need to be amended to change the current Management Areas in the corridor to Management Area 5C-Designated Utility Corridors. The MNF does not have LRMP direction that would require a similar plan amendment to reallocate management prescriptions.

The USFS Regional Foresters of the respective national forests have authority to grant a right-of-way in response to Atlantic's application for natural gas transmission on federal lands under the Mineral Leasing Act of 1920. The Responsible Official for amendment of Forest Service LRMPs is the Forest Supervisor of the applicable national forest. However, the Regional Forester of the applicable national forest may elect to be the Responsible Official for the plan amendments as well, since the Regional Forester will be the Responsible Official for the right-of-way grant.

This NOI initiates the scoping process for the potential LRMP amendments and for the issuance of the right-of-way grant. The decisions will be tiered to the analysis contained in the FERC EIS for the ACP. The Notice of Availability for the FERC draft EIS will contain more detailed information associated with the LRMP amendments.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for Section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the projects' potential effects on historic properties.[3] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the projects develop. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EIS for these projects will document our findings on the impacts on historic properties and summarize the status of consultations under Section 106.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the ACP and proposed USFS LRMP amendments. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington DC on or before June 2, 2016. If you have previously provided comments on the ACP or Supply Header Projects, you do not need to resubmit them.

The USFS is participating as a cooperating agency with the FERC in this public scoping process. With this notice, the USFS is requesting public comments on the issuance of the ROW Grant that would allow the ACP to occupy federal land. The USFS is also requesting public comments on the potential amendments of USFS LRMPs to make provision for the ACP right-of-way on the Monongahela and George Washington National Forests.

Comments on actions by the USFS should be submitted through the FERC comment process and within the timeline described. The submission of timely and specific comments can affect a reviewer's ability to participate in subsequent administrative or judicial review of USFS decisions. Comments concerning USFS actions submitted anonymously will be accepted and considered; however, such anonymous submittals will not provide the commenters with standing to participate in administrative or judicial review of USFS decisions.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the appropriate project docket number (CP15–554–000 for the ACP) with your submission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*. Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature located on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the eFiling feature located on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You must select the type of filing you are making. If you are filing a comment on a particular project, please select "Comment on a Filing;" or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

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[3] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, as well as anyone who submits comments on the projects. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned projects.

Copies of the completed draft EIS will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EIS scoping process, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the "e-filing" link on the Commission's Web site.

Administrative Review of USFS Decisions

Decisions by the USFS to issue ROW Grants and amend LRMPs are subject to administrative review. Pre-decisional objections to the ROW Grant decisions and project-specific MNF and GWNF LRMP amendments that are applicable only to the ACP, as provided under Title 36 of the Code of Federal Regulations Part 219.59(b) (36 CFR 219.59[b]), may be filed under the 36 CFR 218 regulations, Subparts A and B. For objection eligibility (218.5), only those who have submitted timely, specific written comments during any designated opportunity for public comment may file an objection. Issues to be raised in objections must be based on previously submitted specific written comments regarding the proposed project and attributed to the objector, unless the issue is based on new information that arose after a designated opportunity for comment (218.8(c)). The GWNF plan amendment for the reallocation of management areas to Management Area 5C-Designated Utility Corridors would be subject to the pre-decisional objection process under the regulations at 36 CFR 219, Subpart B. For objection eligibility (219.53), only those who have submitted substantive formal comments related to a plan amendment during the opportunities for public comment during the planning process for that decision may file an objection. Objections must be based on previously submitted substantive formal comments attributed to the objector unless the objection concerns an issue that arose after the opportunities for formal comment.

Additional Information

Additional information about the ACP is available from the Commission's Office of External Affairs, at (866) 208–FERC or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search," and enter the docket number, excluding the last three digits (*i.e.*, CP15–554). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm*.

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: May 3, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10784 Filed 5–6–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–873–000.
Applicants: Elba Express Company, L.L.C.
Description: § 4(d) Rate Filing: Fuel Tracker Filing—2016 to be effective 6/1/2016.
Filed Date: 4/26/16.
Accession Number: 20160426–5081.
Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: RP16–874–000.
Applicants: Questar Overthrust Pipeline Company.
Description: § 4(d) Rate Filing:—14.7—Imbalances on Inactive Contracts Version 1.0.0 to be effective 5/26/2016.
Filed Date: 4/26/16.
Accession Number: 20160426–5115.
Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: RP16–875–000.
Applicants: Cameron Interstate Pipeline, LLC.
Description: Annual Report of Interruptible Transportation Revenue Sharing of Cameron Interstate Pipeline, LLC under RP16–875.
Filed Date: 4/26/16.
Accession Number: 20160426–5138.
Comments Due: 5 p.m. ET 5/9/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10768 Filed 5–6–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–63–000]

Indicated RTO Transmission Owners; Notice of Petiton for Declaratory Order

Take notice that on April 26, 2016, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2015), the Indicated RTO Transmission Owners (RTO)[1] filed a petition for declaratory order finding that RTO may use single-issue ratemaking in future filings under section 205 of the Federal Power Act to modify existing Commission jurisdictional rates, all as more fully explained in the petition.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.or,* call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on May 26, 2016.

Dated: May 2, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10769 Filed 5–6–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] American Electric Power Service Corporation, on behalf of its affiliates Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, AEP Appalachian Transmission Company, AEP Indiana Michigan Transmission Company, AEP Kentucky Transmission Company, AEP Ohio Transmission Company, AEP West Virginia Transmission Company, Public Service Company of Oklahoma, Southwestern Electric Power Company, AEP Oklahoma Transmission Company, Inc., AEP Southwestern Transmission Company, Inc., Transource Missouri, LLC, Transource Kansas, LLC, Transource Wisconsin, LLC, Transource West Virginia, LLC; Kansas City Power & Light Company and KCP&L Greater Missouri Operations Company; Oklahoma Gas & Electric Company; Westar Energy, Inc., Prairie Wind Transmission, LLC, and Kanstar Transmission.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–59–000]

MidAmerican Energy Company; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On May 2, 2016, the Commission issued an order in Docket No. EL16–59–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into the justness and reasonableness of MidAmerican Energy Company's proposed rate reduction. *MidAmerican Energy Company,* 155 FERC ¶ 61, 122 (2016).

The refund effective date in Docket No. EL16–59–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: May 3, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10785 Filed 5–6–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY ADMINISTRATION

Western Area Power Administration

Record of Decision for the San Luis Transmission Project (DOE/EIS–0496)

AGENCY: Western Area Power Administration, DOE.

ACTION: Record of decision and statement of floodplain findings.

SUMMARY: The Western Area Power Administration (Western), a power marketing administration within the U.S. Department of Energy (DOE), and the San Luis & Delta-Mendota Water Authority (Authority), a California joint powers agency, have prepared a joint Environmental Impact Statement (EIS)/Environmental Impact Report (EIR) for the San Luis Transmission Project (SLTP or Proposed Project). Western is the Federal lead agency under the National Environmental Policy Act (NEPA), and the Authority is the state lead agency under the California Environmental Quality Act (CEQA). The Bureau of Reclamation (Reclamation) is a NEPA Cooperating Agency. The California Department of Water Resources (DWR) is a CEQA Responsible Agency. Western proposes to construct, own, operate, and maintain approximately 95 miles of new transmission lines within easements ranging from 125 to 250 feet wide through Alameda, San Joaquin, Stanislaus, and Merced Counties along the foothills of the western San Joaquin Valley. Western also would upgrade or expand its existing substations, make the necessary arrangements to upgrade or expand existing Pacific Gas & Electric Company (PG&E) substations, or construct new substations to accommodate the interconnections of these new transmission lines. The Notice of Availability (NOA) of the Final EIS/EIR was published in the **Federal Register** on March 25, 2016 (81 FR 16175). After considering the environmental impacts, Western has decided to construct, operate, and maintain the transmission line and other project components within the corridors identified as the Agency Preferred Alternative in the Final EIS/EIR.

FOR FURTHER INFORMATION CONTACT: Mr. Donald Lash, NEPA Document Manager, Western Area Power Administration, Sierra Nevada Region, 114 Parkshore Drive, Folsom, CA 95630–4710; telephone (916) 353–4048. Hard copies of the EIS/EIR are available from Mr. Lash upon request. For general information on DOE's NEPA review process, please contact Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance, GC–20, U.S. Department of Energy, Washington, DC 20585; telephone (202) 586–4600 or (800) 472–2756.

For information related to Reclamation's participation, contact Mr. Russell Grimes, Chief, Environmental Compliance and Conservation, Bureau of Reclamation, Mid-Pacific Region, 2800 Cottage Way, Sacramento, CA 95818, telephone (916) 978–5051, email at *rwgrimes@usbr.gov.* For information related to the Authority's participation and the CEQA process, contact Ms. Frances Mizuno, General Manager, San Luis & Delta-Mendota Water Authority, 15990 Kelso Road, Byron, CA 94514, telephone (209) 832–6200.

SUPPLEMENTARY INFORMATION: Western delivers Federal electric power (mostly hydroelectric power) to Federal preference customers defined to include municipalities, rural electric cooperatives, public utilities, irrigation districts, Federal and state agencies, and Native American tribes. Western also is responsible for making the necessary arrangements to deliver federal power to Federally authorized projects.

Reclamation is the largest wholesaler of water in the country, supplying more than 31 million people, and providing one out of five western farmers with irrigation water for 10 million acres of farmland. Reclamation is also the second largest producer of hydroelectric power in the western United States with 53 power plants that provide more than 40 billion kilowatt hours annually and generate nearly a billion dollars in power revenues. Reclamation's mission is to assist in meeting the increasing water demands of the West while protecting the environment and the public's investment in these structures. Reclamation emphasizes fulfilling its water delivery obligations, water conservation, water recycling, and reuse goals; developing partnerships with customers, states, and Native American tribes; and finding ways to address the competing needs for limited water resources.

The Authority is a California joint powers agency, comprised of water agencies representing approximately 28 Federal and exchange water service contractors within the western San Joaquin Valley, San Benito and Santa Clara counties. One of the primary purposes of establishing the Authority was to assume the operation and maintenance responsibilities of certain Reclamation facilities located in the Central Valley, and to do so at an optimum level and at a lower cost than Reclamation. The Authority also has the mission of pursuing additional reliable water supply for its member districts and delivering the water with a reliable system in a cost efficient manner.

Reclamation entered into a contract with PG&E in 1965 for power transmission and distribution service between Western's Tracy Substation and Reclamation's San Luis Unit (SLU) facilities. The existing transmission contract with PG&E expired in March 2016, and PG&E has stated it will not be renewed. Without the contract or a federal transmission line to serve the primary SLU facilities, the Federal Government will have to take transmission service under the California Independent System Operator Tariff. This would substantially increase Reclamation's transmission costs, which are paid by its water service contractors, including members of the Authority. Reclamation submitted a transmission service request to Western to consider various transmission service arrangements, including the construction of new Federal transmission lines for Reclamation's continued delivery of federal water after the PG&E contract expires. To meet its purpose and need Western must respond to Reclamation's request for transmission service consistent with Western's Open Access Transmission Tariff and existing laws. In October 2013, Duke American Transmission Company (DATC) submitted a transmission service request to Western for transmission service within the same corridor as requested by Reclamation. Western evaluated both requests jointly in order to determine if it can satisfy Reclamation's need and DATC's request with a single project.

The Notice of Intent (NOI) to prepare an EIS/EIR was published in the **Federal Register** on November 22, 2013 (78 FR 70035). Formal public scoping for the EIS/EIR began with the publication of the NOI and ended on January 21, 2014. Two public scoping meetings were held on January 8 and 9, 2014. Western distributed notices to 75 local agencies, 8 state agencies, 6 Federal agencies, 21 organizations, and 39 elected officials. Western also sent postcards announcing the public scoping meetings and comment period to all property owners within or adjacent to the Proposed Project or alternative routes, and published advertisements on the meetings and comment period in five local newspapers. The NOA for the Draft EIS/EIR was published in the **Federal Register** on July 17, 2015 (80 FR 42491). The NOA established a 45-day public comment period that ended August 31, 2015. Two public meetings on the Draft EIS/EIR were held in Tracy, California, on August 10, 2015 and Los Banos, California, on August 11, 2015. Notice of the meeting was provided through an advertisement in the local newspaper and direct mailing to approximately 475 addressees. Four individuals provided oral comments during the public meetings. Western received 26 comment letters and emails on the Draft EIS/EIR during the comment period, and Western considered all comments received in developing the Final EIS/EIR. The NOA for the Final EIS/EIR was published in the **Federal Register** on March 25, 2016 (81 FR 16175). Approximately 500 notifications were sent to landowners in the Project area and other agencies and stakeholders, and notices were published in online and printed versions of the local newspaper on March 25, 2016. Copies of the Final EIS/EIR were available for review at two local reading rooms and were available for download from Western SNR's Web site and the project Web site. A copy of the EIS/EIR was sent to those who requested one.

Proposed Action

The SLTP would consist of: (1) A new 500-kilovolt (kV) transmission line about 65 miles in length between the new Tracy East and Los Banos West Substations; (2) a new 230-kV transmission line about 3 miles in length between the new Los Banos West Substation and Western's existing San Luis Substation; (3) a new 230-kV transmission line about 20 miles in length between Western's existing San Luis Substation and Western's existing Dos Amigos Substation or a new 230-kV transmission line about 18 miles in length between the new Los Banos West Substation and Western's existing Dos Amigos Substation; (4) an interconnection with the existing Western 500-kV Los Banos-Gates No. 3 transmission line just south of PG&E's existing Los Banos Substation into the new Los Banos West Substation; and (5) a new 70-kV transmission line about 7 miles in length between the existing San Luis and O'Neill Substations.

Additional components of the SLTP would include new 230-kV line terminal bays at Western's San Luis and Dos Amigos Substations, as well as a new 230/70-kV transformer bank and interconnection facilities at the San Luis Substation. The SLTP also would include ancillary facilities, such as communication facilities, improvements to existing access roads, new permanent access roads, and temporary access roads to facilitate construction activities. Western would acquire the necessary easements and fee land for the Proposed Project.

Western implements Environmental Protection Measures (EPMs) and Construction Standards to reduce environmental consequences associated with its construction and maintenance activities. The Final EIS analysis of environmental consequences considered the EPMs listed in Table 2–5 and the Construction Standards presented in Appendix F to the Final EIS as integral components of the Proposed Action. These EPMs and Construction Standards would be implemented as part of the Proposed Project.

Description of Alternatives

Western analyzed six corridor alternatives and the No Action/No Project alternative in the EIS/EIR. An additional seven alternatives were considered in a screening process and eliminated from further review based on feasibility considerations. Western divided the Proposed Project, at common points of the corridors, into four segments (North, Central, San Luis, South) and examined available alternatives. Alternative corridors are presented by segment in Table 1, with the Agency Preferred Alternative shown in highlight:

Table 1: Route Corridors and Alternatives

Route Corridor	Alternative	Alternative	Alternative	Alternative
North Segment	Proposed Route	No Action	No Alternatives Identified	
Central Segment	Proposed Route	No Action	Patterson Pass Road	
San Luis Segment (500kV)	Proposed Route	No Action	Butts Road	West of Cemetery
San Luis Segment (70kV)	Proposed Route	No Action	West of O'Neil Forebay	
South Segment	Proposed Route	No Action	San Luis to Dos Amigos Alternative	Billy Wright Road

The No Action/No Project Alternative is the Environmentally Preferred Alternative because it would avoid any adverse direct, indirect, or cumulative environmental impacts. However, the No Action/No Project Alternative would not achieve the purpose and need or basic project objectives. Therefore, an environmentally preferred action alternative was identified among the other (*i.e.*, action) alternatives. The Environmentally Preferred Action Alternative is comprised of:

North Segment—Proposed Route;
Central Segment—Patterson Pass Road Alternative;
San Luis Segment (500-kV)—Proposed Route;
San Luis Segment (70-kV)—Proposed Route; and
South Segment—San Luis to Dos Amigos Alternative.

After analysis of public comments and further internal review of the EIS/EIR, Western has determined its Agency Preferred Alternative is the same as the Environmentally Preferred Action Alternative in the Northern and San Luis (500-kV and 70-kV) segments. In the Central Segment, the Proposed Route is the Agency Preferred Alternative. Although it would be closer to residences and have slight increases in the associated visual and temporary noise impacts, it would have less of an impact on biological resources. In particular, it would impact fewer special-status plant species. Additionally, it would require fewer crossings of the existing high voltage transmission lines, which would increase reliability by providing more space between circuits. In the South Segment, the Billy Wright Road Alternative is the Agency Preferred Alternative. Although it would have greater recreation impacts by crossing the Path of the Padres Trail and slightly greater soil disturbance due to its longer length, it would avoid conflicts with the Wright Solar Park, which is now fully permitted and expected to begin construction in 2016.

The Agency Preferred Alternative is comprised of:

North Segment—Proposed Route;
Central Segment—Proposed Route;
San Luis Segment (500-kV)—Proposed Route;
San Luis Segment (70-kV)—Proposed Route; and
South Segment—Billy Wright Road Alternative.

Mitigation Measures

All methods identified in Final EIS Table 6.1 to avoid, minimize, and mitigate environmental impacts from the selected alternative are adopted in this Record of Decision. Western's standard practices and project-specific protection measures, listed in the Final EIS/EIR, will be implemented as part of the Proposed Action, as will all terms and conditions of any required permits or consultation agreements.

Floodplain Statement of Findings

In accordance with 10 CFR part 1022, Western considered the potential impacts of the Project on floodplains and wetlands. The Project could affect floodplains through ground disturbance associated with construction and operations and maintenance activities, including operation of heavy equipment, grading, and vegetation clearing for access roads, site leveling, auguring of transmission tower foundations, and other infrastructure excavations. The Project will place new structures outside of floodplains where possible. In areas where floodplains cannot be avoided, Western will engineer transmission towers to withstand a 100-year flood. Additionally, new structures will be located and designed so as not to impede flood flows. All construction within a designated 100-year floodplain will be undertaken in consultation with the U.S. Army Corps of Engineers. No floodwater will be blocked, nor will floodwater be diverted outside of an existing floodplain. If avoidance is infeasible, transmission towers will be located and engineered so as not to block or substantially alter the natural drainage pattern. In accordance with Western's Environmental Protection Measures and Construction Standard 13, culverts or bridges will be installed where needed to avoid surface water impacts during construction of transmission line structures.

Decision

Western's decision is to construct the project along the Agency Preferred Alternative described in the Final EIS/EIR. The measures identified in Final EIS Table 6.1 are adopted as part of this decision. The selection of the Agency Preferred Alternative, the adopted measures from Final EIS Table 6.1, and all terms and conditions of required permits and consultation agreements satisfies Western's statutory mission while minimizing harm to the environment. This decision is based on the information in the Final EIS/EIR. The EIS including this Record of Decision was prepared according to the requirements of NEPA (42 U.S.C. 4321, *et seq.*), the Council on Environmental Quality's regulations for implementing NEPA (40 CFR parts 1500–1508) and DOE's procedures for implementing NEPA (10 CFR part 1021).

Dated: April 29, 2016.

Mark A. Gabriel,

Administrator.

[FR Doc. 2016–10802 Filed 5–6–16; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9941–97–OEI]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et. Seq.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Courtney Kerwin (202) 566–1669, or email at *kerwin.courtney@epa.gov* and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB Approvals

EPA ICR Number 1362.10; NESHAP for Coke Oven Batteries (Renewal); 40 CFR part 63, subparts A and L; was approved without change on 1/27/2016; OMB Number 2060–0253; expires on 1/31/2019.

EPA ICR Number 2491.02; Agricultural Worker Protection Standard Training, Notification and Recordkeeping (Final Rule); 40 CFR part 170; was approved without change on 1/21/2016; OMB Number 2070–0190; expires on 1/31/2019.

EPA ICR Number 1360.15; Revision of Information Collection Request for Underground Storage Tanks: Technical and Financial Requirements, and State Program Approval Procedures (Final Rule); 40 CFR parts 280 and 281; was approved without change on 1/14/2016; OMB Number 2050–0068; expires on 1/31/2019.

EPA ICR Number 1656.15; Risk Management Program Requirements and Petitions to Modify the List of Regulated Substances under Section 112(r) of the Clean Air Act (Renewal); 40 CFR part 68; was approved without change on 1/14/2016; OMB Number 2050–0144; expires on 1/31/2019.

EPA ICR Number 1867.06; Voluntary Aluminium Industrial Partnership (VAIP) (Renewal); was approved without change on 1/14/2016; OMB Number 2060–0411; expires on 1/31/2019.

EPA ICR Number 1821.08; NESHAP for Steel Pickling, HCI Process Facilities and Hydrochloric Acid Regeneration Plants (Renewal); 40 CFR part 63, subparts A and CCC; was approved without change on 1/12/2016; OMB Number 2060–0419; expires on 1/31/2019.

EPA ICR Number 2468.02; NPDES Electronic Reporting (Final Rule); 40 CFR parts 122, 123, 127, 403, 501, and 503; was approved without change on 1/11/2016; OMB Number 2020–0035; expires on 1/31/2019.

EPA ICR Number 2507.01; Lead Training, Certification, Accreditation and Authorization Activities (New); 40 CFR part 745; was approved with change on 1/8/2016; OMB Number 2070–0195; expires on 1/31/2019.

EPA ICR Number 0107.11; Air Stationary Source Compliance and Enforcement Information Reporting (Renewal); 40 CFR parts 51, 52, 60, 61, and 63; was approved without change on 1/5/2016; OMB Number 2060–0096; expires on 1/31/2019.

EPA ICR Number 2203.05; Amendments to the Protocol Gas Verification Program, and Minimum Competency Requirements for Air Emission (Renewal); 40 CFR parts 72 and 75; was approved without change on 1/5/2016; OMB Number 2060–0626; expires on 1/31/2019.

EPA ICR Number 1783.08; NESHAP for Flexible Polyurethane Foam Product (Final Rule); 40 CFR part 63, subparts A and III; was approved with change on 1/4/2016; OMB Number 2060–0357; expires on 1/31/2019.

EPA ICR Number 2475.02; Labeling Change for Certain Minimum Risk Pesticides under FIFRA Section 25(b) (New); 40 CFR part 152; was approved with change on 2/22/2016; OMB Number 2070–0187; expires on 2/28/2019.

EPA ICR Number 1426.11; EPA Worker Protection Standards for Hazardous Waste Operations and Emergency Response (Renewal); 40 CFR part 311; was approved without change on 2/3/2016; OMB Number 2050–0105; expires on 2/28/2019.

Comment Filed

EPA ICR Number 2493.02; Categorical Non-Waste Determination for Selected Non Hazardous Secondary Materials (NHSM): Construction and Demolition Wood, Paper Recycling Residuals, and Creosote-Treated Railroad Ties (Additions to List of Section 241.4 Categorical Non-Waste Fuels) (Proposed Rule); 40 CFR parts 63 and 241; OMB filed comment on 1/20/2016.

Courtney Kerwin,

Acting Director, Collections Strategies Division.

[FR Doc. 2016–10755 Filed 5–6–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0188; FRL–9945–83]

Sulfoxaflor; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Idaho State Department of Agriculture to use the pesticide sulfoxaflor (CAS No. 946578–00–3) to treat up to 12,000 acres of alfalfa grown for seed to control lygus bugs. The applicants propose a use of a pesticide, sulfoxaflor, which is now considered to be unregistered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) owing to the vacature of sulfoxaflor registrations by the United States District court for the Central District of California. In accordance with 40 CFR 166.24(a)(7), EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before May 24, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2016–0188, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

II. What action is the agency taking?

Under section 18 of the FIFRA (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. The Idaho State Department of Agriculture has requested the EPA Administrator to issue a specific, exemption for the use of sulfoxaflor on alfalfa grown for seed to control lygus bugs. Information in accordance with 40 CFR part 166 was submitted as part of this request.

The Applicant proposes to make no more than two applications per year of Transform WG, 0.047 to 0.086 pounds of active ingredient per application. 12,000 total acres of alfalfa grown for seed are requested to be treated. Ground applications must be made in a minimum of 15 gallons of water per acre. The use season is May 30, 2016 through August 31, 2016. The chemical is requested to be used in the State of Idaho within the counties of Ada, Canyon, Cassia, Franklin, Jerome, Oneida, Owyhee, Payette, and Twin Falls.

This notice does not constitute a decision by EPA on the application itself. The regulations governing FIFRA section 18 require publication of a notice of receipt of an application for a specific exemption proposing a use of a pesticide that has been subject to a judicial vacature, however, EPA considers public notice appropriate in this instance. Accordingly, the notice provides an opportunity for public comment on the application.

The Agency, will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by the Idaho State Department of Agriculture.

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 28, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2016–10845 Filed 5–6–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0799]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 8, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0799.

Title: FCC Ownership Disclosure Information for the Wireless Telecommunications Services.

Form No.: FCC Form 602.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; and State, Local or Tribal government.

Number of Respondents and Responses: 4,115 respondents and 4,115 responses.

Estimated Time per Response: .5 hours–1.5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of this information is contained in Sections 154(i), 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended. The statutory authority for this collection of this information is contained in Sections 154(i), 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended.

Total Annual Burden: 5,217 hours.

Total Annual Cost: $762,300.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The FCC Form 602 is necessary to obtain the identity of the filer and to elicit information required by Section 1.2112 of the Commission's rules regarding: (1) Persons or entities holding a 10 percent or greater direct or indirect ownership interest or any general partners in a general partnership holding a direct or indirect ownership interest in the applicant ("Disclosable Interest Holders"); and (2) All FCC-regulated entities in which the filer or any of its Disclosable Interest Holders owns a 10 percent or greater interest. The data collected on the FCC Form 602 includes the FCC Registration Number (FRN), which serves as a "common link" for all filings an entity has with the FCC. The Debt Collection Improvement Act of 1996 requires that entities filing with the Commission use an FRN. The FCC Form 602 was designed for, and must be filed electronically by, all licensees that hold licenses in auctionable services.

The FCC Form 602 is comprised of the Main Form containing information regarding the filer and the Schedule A is used to collect ownership data pertaining to the Disclosable Interest Holder(s). Each Disclosable Interest Holder will have a separate Schedule A. Thus, a filer will submit its FCC Form 602 with multiple copies of Schedule A, as necessary, to list each Disclosable Interest Holder and associated information.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer. Office of the Secretary.

[FR Doc. 2016–10817 Filed 5–6–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10490 Bank of Jackson County, Graceville, Florida

Notice is hereby given that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Bank of Jackson County, Graceville, Florida ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of Bank of Jackson County on October 30, 2013. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: May 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–10748 Filed 5–6–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update Listing of Financial Institutions in Liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as "of record" notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: May 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10519	Trust Company Bank	Memphis	TN	4/29/2016

[FR Doc. 2016–10749 Filed 5–6–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 24, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *First Interstate BancSystem, Inc.*, Billings, Montana; to acquire 100 percent of the voting shares of Flathead Bank of Bigfork, Bigfork, Montana.

Board of Governors of the Federal Reserve System, May 4, 2016.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–10828 Filed 5–6–16; 8:45 am]

BILLING CODE 6210–01–P

GOVERNMENT ACCOUNTABILITY OFFICE

Change in Medicaid and CHIP Payment and Access Commission Terms

AGENCY: Government Accountability Office (GAO).

ACTION: Notice on terms of appointments.

SUMMARY: In accordance with the Children's Health Insurance Program Reauthorization Act of 2009, the Comptroller General appoints the 17 members of the Medicaid and CHIP Payment and Access Commission (MACPAC). This notice announces the extension of all current members for an additional 4 months.

DATES: *Effective Date:* May 9, 2016.

ADDRESSES: The Government Accountability Office is at 441 G St. NW., Washington, DC 20548. The Medicaid and CHIP Payment and Access Commission is at 1800 M St. NW., Suite 650 South, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Government Accountability Office: Mary Giffin, (202) 512–3710. Medicaid and CHIP Payment and Access Commission: Anne L. Schwartz, Executive Director, (202) 350–2000.

SUPPLEMENTARY INFORMATION: The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) established MACPAC to report to Congress on Medicaid and CHIP access and payment policies and make recommendations to Congress, the Secretary of Health and Human Services, and the states concerning access to Medicaid and CHIP covered services. CHIPRA gave the Comptroller General of the United States responsibility for appointing MACPAC's 17 members. Appointments are for 3 years, except for members appointed to fill vacancies and for initial members, for which staggered terms were required.

Pursuant to that authority, all initial appointments were effective January 1, 2010, but were staggered so that 5 ended in December 2010, 6 ended in December 2011, and 6 ended in December 2012. The Comptroller General has continued to make appointments effective in January of each year since the initial appointments.

In consultation with the Commission, the Comptroller General has concluded that members' terms should be changed to more closely match the Commission's business cycle. The current January 1 to December 31 terms are out of step with that cycle; the Commission carries out significant planning activities in the summer and finalizes its two reports in late January and April of each year. Terms that begin May 1 and end April 30 would coincide more closely with the Commission's work schedule and thus make Commission operations more efficient and effective.

To better align the terms of service with Commission operations, the terms of all current members are hereby extended for 4 months. The following members' terms will expire on April 30, 2017: Sharon Carte, Andrea Cohen, Herman Gray, Norma Martinez Rogers, and Sara Rosenbaum. The following members' terms will expire on April 30, 2018: Gustavo Cruz, Leanna George, Marsha Gold, Charles Milligan, Sheldon Retchin, and Peter Szilagyi. The following members' terms will expire on April 30, 2019: Brian Burwell, Toby Douglas, Christopher Gorton, Stacey Lampkin, Penny Thompson, and Alan Weil.

Subsequent appointments will be for 3 years.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2016–10535 Filed 5–6–16; 8:45 am]

BILLING CODE 1610–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9097–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from January through March 2016, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	Mitch Bryman	(410) 786–5258
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton	(410) 786–2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin	(410) 786–7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786–8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis	(410) 786–8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton	(410) 786–2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786–8564
All Other Information	Annette Brewer	(410) 786–6580

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

Dated: April 29, 2016.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: April 24, 2015 (80 FR 23013) August 3, 2015 (80 FR 45980) November 13, 2015 (80 FR 70218) and February 4, 2016 (81 FR 6009). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the Web site to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (January Through March 2016)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How To Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15–1, Pub 15–2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703–605–6050). You can download copies of the listed material free of charge at: *http://cms.gov/manuals.*

How To Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at *http://www.gpo.gov/libraries/*

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP)—January 2016 (CMS-Pub. 100–04) Transmittal No. 3377.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our Web site at *www.cms.gov/Manuals.*

Transmittal No.	Manual/subject/publication No.
	Medicare General Information (CMS-Pub. 100–01)
97	Internet Only Manual (IOM) Publication 100–01–General Information, Eligibility, and Entitlement, Chapter 7—Contract Administrative Requirements, Section 40–Shared System Maintainer Responsibilities for Systems Releases. Standardized Terminology for Claims Processing Systems. Standard Terminology Chart. Release Software. Implementing Validated Workarounds for Shared System Claims Processing by All Medicare DME MACs. Shared System Testing Requirements for Shared System Maintainers, Single Testing Contractor (STC)/Beta Testers, and Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs). Shared System Testing Requirements for Shared System Maintainers, Single Testing Contractor (STC), and DME MACs. Minimum Testing Standards for Shared System Maintainers and the Single Testing Contractor (STC)/Beta Testers. Testing Standards Applicable to all Beta Testers. Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) (User) Testing Requirements 7/40.3.6/Testing Requirements Applicable to all CWF Data Centers (Hosts). Timeframe Requirements for all Testing Entities. Testing Documentation Requirements. Definitions. Test Case Specification Standard. Next Generation Desktop (NGD) Requirements.

Transmittal No.	Manual/subject/publication No.
	Shared System Maintainer and Part A/Part B (A/B)/Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) and the Single Testing Contractor (STC) Responsibilities for Systems Releases.
	Medicare Benefit Policy (CMS-Pub. 100–02)
218	Calendar Year (CY) 2016 Eligibility Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Low-Volume Payment Adjustment (LVPA). ESRD PPS Case-Mix Adjustments.
219	Calendar Year (CY) 2016 Eligibility Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Low-Volume Payment Adjustment ESRD PPS Case-Mix Adjustments (LVPA).
220	Rural Health Clinic and Federally Qualified Health Center—Medicare Benefit Policy Manual Update.
221	Telehealth Services.
	Medicare National Coverage Determination (CMS-Pub. 100–03)
189	Screening for Cervical Cancer With Human Papillomavirus (HPV) Testing-National Coverage Determination (NCD).
190	Screening for the Human Immunodeficiency Virus (HIV) Infection.
	Medicare Claims Processing (CMS-Pub. 100–04)
3436	National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™—A Multi-target Stool DNA Test.
3437	January 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.0.
3438	Emergency Update to the CY 2016 Medicare Physician Fee Schedule Database (MPFSDB).
3439	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits.
3440	New Waived Tests.
3441	Update to Pub. 100–04, Chapter 02 Admission and Registration Requirements, for Provider Verification of Beneficiary Eligibility and Entitlement. Purpose of Chapter. Definition of Provider and Supplier. General Admission and Registration Rules. Changes to HICNs. Contractor Procedures for Obtaining Missing or Incorrect Claim Numbers. Prohibition Against Waiver of Health Insurance Benefits as a Condition of Admission. Hospital and Skilled Nursing Facility (SNF) Verification of Prior Hospital Stay. Information for Determining Deductible and Benefit Period Status. A/B MAC (A) or (HHH) Requests to Verify Patient's HICN. B MAC (A) or (HHH) Learns Beneficiary is an HMO Enrollee. Retroactive Entitlement. 2/30/Provider/Supplier Obtaining/Verifying the HICN and Entitlement Status. 2/30.1/Cross-Reference of HICN. Health Insurance (HI) Card. Temporary Eligibility Notice. Reserved. Part A Inquiry (HIQA) Screen Display. Part A Inquiry Reply (HUQAR) Data. Health Insurance Query for Home Health Agencies (HIQH). Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. Reserved. HMO-Related Master File Corrections. Provider Problems Obtaining Entitlement Information. Reserved. Reserved. Reserved. SSO Assistance in Resolving Entitlement Status Problems. Reserved.

Transmittal No.	Manual/subject/publication No.
	Reserved. Reserved. Reserved. Reserved.
3442	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3443	Manual Update to Pub. 100–04, Chapter 20, to Include Used Rental Equipment.
3444	Payment for Purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Furnished to Medicare Beneficiaries Residing Outside the U.S.—Expatriate Beneficiaries.
3445	Off-Cycle Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2016 Pricer Budget Neutrality Offset.
3446	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3447	New Physician Specialty Code for Dentist Physician Specialty Codes.
3448	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3449	Off-Cycle Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2016 Pricer.
3450	April 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files.
3451	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3452	Additional Fields Added to the Outlier Reconciliation Lump Sum Utility Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments.
3453	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3454	Correction to Applying Therapy Caps to Maryland Hospitals and Billing Requirement for Rehabilitation Agencies and Comprehensive Outpatient Rehabilitation Facilities (CORFs). Payments on the MPFS for Providers With Multiple Service Locations. Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services—General.
3455	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3456	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3457	New Condition Code for Reporting Home Health Episodes With No Skilled Visits.
3458	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3459	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
3460	Screening for Cervical Cancer With Human Papillomavirus (HPV). Testing—National Coverage Determination (NCD). Screening for Cervical Cancer with Human Palillomavirus Testing. Screening Pap Smears: Healthcare Common Procedure Coding. System (HCPCS) Codes for Billing. Screening Pap Smears: Diagnoses Codes. TOB and Revenue Codes for Form CMS–1450. MSN Messages. Remittance Advice Codes.
3461	Screening for the Human Immunodeficiency Virus (HIV) Infection. Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests. Billing Requirements. Payment Method. Types of Bill (TOBs) and Revenue Code. Diagnosis Code Reporting. Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs).
3462	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3463	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
3464	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3465	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
3466	Common Edits and Enhancements Modules (CEM) Code Set Update.
3467	Healthcare Provider Taxonomy Codes (HPTCs) April 2016 Code Set Update.
3468	Medicare Internet Only Manual (IOM) Publication 100–04 Chapter 27 Contractor Instructions for CWF.
3469	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB)—April CY 2016 Update.
3470	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3471	April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS).
3472	Billing Instructions for IMRT Planning Billing for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS) Planning and Delivery.
3473	July Quarterly Update to 2016 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement.
3474	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3475	Updates to Pub. 100–04, Chapters 4 and 5 to Correct Remittance Updates to Pub. 100–04, Chapters 4 and 5 to Correct Remittance. Advice Messages. Remittance Advice Coding Used in this Manual. Editing Of Hospital Part B Inpatient Services: Reasonable and Necessary Part A Hospital Inpatient Denials. Editing Of Hospital Part B Inpatient Services: Other Circumstances in Which Payment Cannot Be Made under Part A. Assistant at Surgery Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages. Co-surgeon Services Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages. Codes. Claims Processing Requirements for Financial Limitations/Multiple Procedure Payment Reductions for Outpatient Rehabilitation Services.

Transmittal No.	Manual/subject/publication No.
	Coding Guidance for Certain CPT Codes—All Claim Advice Messages.
3476	Telehealth Services.
	List of Medicare Telehealth Services.
	Payment for ESRD-Related Services as a Telehealth Service.
	Payment for Subsequent Hospital Care Services and Subsequent Nursing Facility Care Services as Telehealth Services.
	Payment for Diabetes Self-Management Training (DSMT) as a Telehealth Service.
	Originating Site Facility Fee Payment Methodology.
	Payment Methodology for Physician/Practitioner at the Distant Site.
	Submission of Telehealth Claims for Distant Site Practitioners.
3477	April 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.1.
3478	April 2016 Update of the Ambulatory Surgical Center (ASC) Payment System.
3479	New Waived Test.
3480	Instructions for Downloading the Medicare ZIP Code File for July 2016.
3481	Updates to Pub. 100–04, Chapters 3, 6, 7 and 15 to Correct Remittance Advice Messages.
	Payment for Blood Clotting Factor Administered to Hemophilia.
	Inpatients.
	Pancreas Transplants Kidney Transplants.
	Pancreas Transplants Alone (PA).
	Intestinal and Multi-Visceral Transplants.
	Billing for Abortion Services.
	Remittance Advices.
	Remittance Advice Impact.
	Recording Determinations of Excepted/Nonexcepted Care on Claim Records.
	Reject and Unsolicited Response Edits.
	Edit for Clinical Social Workers (CSWs).
	Editing of Skilled Nursing Facilities Part B Inpatient Services.
	Additional Introductory Guidelines.
	ZIP Code Determines Fee Schedule Amounts.
	Coding Instructions for Paper and Electronic Claim Forms.
3482	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.2, Effective July 1, 2016.
3483	April 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.1.
3484	Medicare Internet Only Manual Publication 100–04 Chapter 26—Completing and Processing Form CMS–1500 Data Set.
3485	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2016.
3486	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3487	Corrections to Recoding in the Home Health (HH) Pricer Program.
3488	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP)—July 2016.
Medicare Secondary Payer (CMS-Pub. 100–05)	
00	None.
Medicare Financial Management (CMS-Pub. 100–06)	
258	Notice of New Interest Rate for Medicare Overpayments and Underpayments 2nd Qtr Notification for FY 2016.
259	Internet Only Manual Pub. 100–06, Chapter 4 Revisions to Reflect the New Debt Referral Requirements Mandated by the Digital Accountability and Transparency Act of 2014 (DATA Act).
	Requirements for Collecting Part A and B Non-MSP Provider Overpayments.
	Required Timeframes for Debt Collection Process for Provider Non-MSP Overpayments.
	Referral Requirements.
	Debts RTA by Treasury as paid in Full (RP), Satisfied Payment Agreement (RS) or Satisfied Compromise (RC)—Exhibit 1 Intent to Refer Letter (IRL).
260	Revision to Chapter 3 Section 200: Limitation on Recoupment—Medicare Overpayments Manual.
261	Monitoring Accounts Receivable that are in a Redetermination or Reconsideration Status.
262	New Physician Specialty Code for Dentist Physician/Limited License Physician Specialty Codes.
263	Contractor Reporting of Operational and Workload Data (CROWD) Form 5.
	Update with Revisions to Pub. 100–06 Medicare Financial Management Manual, Chapter 6.
264	Extended Repayment Schedule (ERS) Manual Updates.
	Establishing an Extended Repayment Schedule (ERS)—(formerly known as an Extended Repayment Plan (ERP).
	ERS Required Documentation—Physician is a Sole Proprietor.
	ERS Required Documentation—Provider is an Entity Other Than a Sole Proprietor.
265	Contractor Reporting of Operational and Workload Data (CROWD) Form 5.
	Update with Revisions to Pub. 100–06 Medicare Financial Management Manual, Chapter 6.
	Medicare Contractor Transaction Report (CROWD Form 5).
	Heading.
	Body of Report.
Medicare State Operations Manual (CMS-Pub. 100–07)	
152	Revisions to the State Operations Manual (SOM) Chapter 2 Numbering System for CMS Certification Numbers (CCN).

Transmittal No.	Manual/subject/publication No.
	CCN for Medicare Providers.
153	Revisions to the State Operations Manual (SOM) Chapter 9 Exhibits.
	Medicare Program Integrity (CMS-Pub. 100–08)
635	Clarification to Language Regarding Proof of Delivery Requirements in Pub. 100–08, Chapter 4, Section 4.26.1. Proof of Delivery and Delivery Methods.
636	Update to Pub. 100–08, Chapter 15. Medicare Contractor Duties. Correspondence Address and E-mail Addresses. Tax Identification Numbers (TINs) of Owning and Managing. Organizations and Individuals. Form CMS–855A and Form CMS–855B Signatories. Delegated Officials. Technicians. Supervising Physicians. Processing Form CMS–855R Applications. Inter-Jurisdictional Reassignments. Form CMS–855 Applications That Require a Site Visit. Form CMS–855 Applications That Do Not Require a Site Visit. General Timeliness Principles. Receipt/Review of Internet-Based PECOS Applications. Verification of Data/Processing Alternatives. Special Program Integrity Procedures. Tie-In/Tie-Out Notices and Referrals to the State/RO. Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS). Tie-In/Tie-Out Notices and Referrals to the State/RO. Processing of Registration Applications. Disposition of Registration Applications. Revocation of Registration. Registration Letters. Returns. Denials. Non-Certified Suppliers and Individual Practitioners. Existing or Delinquent Overpayments. Contractor Communications. Application Fees. Movement of Providers and Suppliers into the High Level. Web Sites. Release of Information. Model Letter Guidance. Approval Letter Guidance. Appeals Process. Corrective Action Plans (CAPs). Reconsideration Requests—Non-Certified Providers/Suppliers. Corrective Action Plans (CAPs). Reconsideration Requests—Certified Providers and Certified Suppliers. HHA Ownership Chang. Revocations. Other Identified Revocations. External Reporting Requirements. Reserved for Future Use.
637	Comprehensive Error Rate Testing (CERT) program Treatment of Claims in the Prior Authorization Model.
638	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
639	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
640	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
641	Proof of Delivery in Nursing Facilities.
642	Medicare Program Integrity Changes—Pub. 100–08 Chapter 7.
	Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100–09)
	None.
	Medicare Quality Improvement Organization (CMS-Pub. 100–10)
	None.
	Medicare End Stage Renal Disease Network Organizations (CMS Pub. 100–14)
	None.

Transmittal No.	Manual/subject/publication No.
Medicaid Program Integrity Disease Network Organizations (CMS Pub. 100–15)	
	None.
Medicare Managed Care (CMS-Pub. 100–16)	
	None.
Medicare Business Partners Systems Security (CMS-Pub. 100–17)	
	None.
Demonstrations (CMS-Pub. 100–19)	
133	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
134	Medicare Care Choices Model (MCCM)—Per Beneficiary per Month Payment (PBPM)—Implementation.
135	Affordable Care Act Bundled Payments for Care Improvement Initiative—Recurring File Updates Models 2 and 4 April 2016 Updates.
136	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
137	Implementation of the Part B Drug Payment Model (Phase 1).
138	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
139	Oncology Care Model (OCM) Monthly Enhanced Oncology Services (MEOS) Payment Implementation.
140	Comprehensive Care for Joint Replacement Model (CJR) Provider Education.
141	Medicare Care Choices Model (MCCM)—Per Beneficiary per Month Payment (PBPM)—Implementation.
One Time Notification (CMS-Pub. 100–20)	
1590	Implementation of Procedures for Undeliverable Medicare Summary Notices (uMSNs).
1591	Changes to the Medicare Electronic Health Record (EHR) Incentive Program Payment Adjustment beginning January 1, 2016.
1592	Award of Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Contract for Jurisdiction D.
1593	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2016.
1594	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1595	Issuing Continuing Compliance Letters to Specific Providers and Suppliers.
1596	Required Billing Updates for Rural Health Clinics.
1597	System Specific Enhancement 2014: Create A Single Trailer-Generating Module in Common Working File (CWF).
1598	Shared System Enhancement 2015 Resolve Operating Report (ORPT) Issues, Analysis and Design.
1599	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1600	Award of Medicare Administrative Contractor (MAC) Contract for Jurisdiction 15.
1601	Payment Clarification for the Purchase of Used Inexpensive and Routinely Purchased Durable Medical Equipment (DME) when Previously Rented.
1602	Part B Detail Line Expansion—MCS Phase 4.
1603	Part B Detail Line Expansion—MCS Phase.
1604	Part B Detail Line Expansion—MCS Phase 1.
1605	Common Working File (CWF) Daily Beneficiary Extract Files Reaching Maximum Record Size, Analysis and Design for Possible Data Reorganization.
1606	Shared System Enhancement 2015 Edit Control/Override Table, Analysis and Design.
1607	Shared System Enhancement 2015 Improve Efficiency of Drug Code Provider, and Procedure and Diagnosis Codes Processing, Analysis and Design.
1608	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1609	Accredited Standards Committee (ASC) X12 Healthcare Claims Acknowledgement (277CA) Flat File Update.
1610	System Specific Enhancement 2014: Fiscal Intermediary Standard System (FISS) Edit/Rules Engine Analysis and Design.
1611	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1612	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1613	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1614	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1615	Advance Care Planning (ACP) Services furnished by Rural Health Clinics (RHCs).
1616	Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers.
1617	System Specific Enhancement 2014: String Testing Automation.
1618	System Specific Enhancement 2015: Replace FISS ACS/Development Letters with HP Exstream, Analysis Only.
1619	Revision to Fiscal Intermediary Shared System (FISS) Lab Travel Allowance Editing to Include New Specimen Collection Code G0471.
1620	Shared System Enhancement 2015: National Coverage Determination (NCD) Analysis Process.
1621	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
1622	Shared System Enhancement 2015 Analysis and Design HUOPCUT Hospice Period and Health Maintenance Organization (HMO) Processing.
1623	Using scrubbed Medicare beneficiary/legal rep address data within the Fee-For-Service (FFS) systems—Analysis and Design.

Transmittal No.	Manual/subject/publication No.
1624	System Specific Enhancement 2015: Fiscal Intermediary Standard System (FISS) Enhanced Purge Process.
1625	Identifying "No Documentation" Medical Necessity Denials for Claims Flagged for Recovery Auditor Review.
1626	Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category.
1627	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Implementation of Round 2 Recompete of the DMEPOS CBP Program and National Mail Order (NMO) Recompete.
1628	Identification of Obsolete Shared System Maintainer (SSM) On-Request Jobs—VMS.
1629	Identification of Obsolete Shared System Maintainer (SSM) Reports—VMS.
1630	Coding Revisions to National Coverage Determinations.
1631	Shared System Enhancement 2015 Edit Control/Override Table, Analysis and Design.
1632	Shared System Enhancement 2015 Resolve Operating Report (ORPT) Issues, Analysis and Design.
1633	Settlement Effectuation Instructions for the Department of Health and Human Services' (DHHS) Office of Medicare Hearings and Appeals (OMHA) Settlement Conference Facilitation (SCF) Pilot Related to Part A Appeals (Phase 3).
1634	Implementation of the Award for Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload.
1635	VIPS Medicare System (VMS), Analysis and Design for Jurisdiction A (JA) and Jurisdiction B (JB) Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) Transitions.
1636	Implementation of the Award for Jurisdiction B Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload.
1637	Required Billing Updates for Rural Health Clinics.
1638	Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category.
1639	Reporting Principal and Interest Amounts When Refunding Previously Recouped Money on the Remittance Advice (RA).
1640	End Stage Renal Disease (ESRD) Cost Audits.
	Medicare Quality Reporting Incentive Programs (CMS-Pub. 100–22)
53	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
54	Fiscal Year 2017 and After Payments to Inpatient Rehabilitation Facilities (IRFs) That Do Not Submit Required Quality Data—This CR Rescinds and Fully Replaces CR 9106.
55	Fiscal Year 2017 and After Payments to IRFs That Do Not Submit Required Quality Data.
	Information Security Acceptable Risk Safeguards (CMS-Pub. 100–25)
	None.

Addendum II: Regulation Documents Published in the Federal Register (January through March 2016)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at *www.gpo.gov/fdsys*. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through *GPO Access*. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at *http://www.gpoaccess.gov/fr/index.html*. The following Web site *http://www.archives.gov/federal-register/* provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our Web site at: *http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-1Q16QPU.pdf*

For questions or additional information, contact Terri Plumb (410–786–4481).

Addendum III: CMS Rulings (January through March 2016)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings*. For questions or additional information, contact Tiffany Lafferty (410–786–7548).

Addendum IV: Medicare National Coverage Determinations (January through March 2016)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS Web site. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: *www.cms.gov/medicare-coverage-database/*. For questions or additional information, contact Wanda Belle (410–786–7491).

Title	NCDM section	Transmittal number	Issue date	Effective date
Screening for the Human Immunodeficiency Virus (HIV) Infection.	NCD 210.7	R190	02/05/2016	04/13/2015
Screening for Cervical Cancer With Human Papillomavirus (HPV) Testing—National Coverage Determination (NCD).	NCD 210.2.1	R189	02/02/2016	07/09/2015

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2016)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410–786–6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start date
BB16806	MarrowStim P.A.D. Kit: Concentration of autologous bone marrow aspirate (cBMA)	01/22/2016
G130034	BIOFREEDOM Drug Coated Coronary Stent System	02/10/2016
G150002	Silhouette Instalift	01/08/2016
G150154	RA–308 Excimer Laser System and DABRA Catheter Model 101	01/08/2016
G150269	Sodium Hyaluronate (1%) Ophthalmic Viscoelastc Devices (OVD), Sodium Hyaluronate (2.3%) Ophthalmic Viscoelastic Devices (OVD).	01/06/2016
G150270	Embozene Microspheres	01/08/2016
G150273	Medtronic Activa PC+S Deep Brain Stimulation System	01/15/2016
G150275	Optune (Novocure's Tumor Treating Electric Fields [TTFIELDS] Therapy)	03/24/2016
G150278	SAPIEN 3 Transcatheter Heart Valve and Accessories	01/14/2016
G150282	Berlin Heart EXCOR Pediatric Ventricular Assist Device	01/28/2016
G160002	FlowTriever Retrieval/Aspiration System	02/03/2016
G160004	Embosphere Microspheres	02/04/2016
G160008	Investigational LabCorp MGMT Methylation-Specific PCR Companion Diagnostic Assay.	02/10/2016
G160009	Medtronic PC+S Deep Brain Stimulation system	02/11/2016
G160011	CP950 Sound Processor (Kanso)	02/17/2016
G160015	JetStream (Boston Scientific) Atherectomy	02/19/2016
G160018	Deep brain stimulation (DBS) in patients with refractory chronic neuropathic pain	03/23/2016
G160019	CT–DBS for Traumatic Brain Injury using the Medtronic Activa PC+S System	02/26/2016
G160021	A Feasibility Study to Evaluate Safety and Initial Effectiveness of MR-Guided Focused Ultrasound Ablation Therapy in the Treatment of Subcortical Lesional Epilepsy.	03/02/2016
G160022	CoreValve Evolut R System, Medtronic CoreValve System	02/17/2016
G160023	NeuroStar TMS Therapy System with the NeuroStar XPLOR Clinical Research System.	03/04/2016
G160025	Medtronic DBS Lead Model 3387	03/04/2016
G160028	NeuroBlate System	03/09/2016
G160029	VENTANA HA CDx Assay	03/10/2016
G160033	Veterans Administration Lung Cancer Surgery or Stereotactic Radiotherapy (VALOR).	03/09/2016
G160035	Misago RX Self-expanding Peripheral Stent	03/17/2016
G160038	MYELOTEC VIDEO GUIDED CATHETER; MYELOTEC MYELOSCOPE	03/17/2016
G160039	Medtronic TAVR 2.0 System	03/16/2016
G160041	The Ulthera System; DS 4–4.5S, Simulines Transducer;DS 4–3.0S, Simulines Transducer; DS 4–4.5, Standard Transducer; DS 7–3.0, Standard Transducer.	03/18/2016
G160042	LUMENATI SYSTEM	03/18/2016
G160043	Senza Spinal Cord Stimulation (SCS) System	03/23/2016
G160045	NeuroStar TMS Therapy System with the NeuroStar XPLOR Clinical Research System.	03/24/2016

Addendum VI: Approval Numbers for Collections of Information (January through March 2016)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at *www.reginfo.gov/public/do/PRAMain.* For questions or additional information, contact Mitch Bryman (410–786–5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (October through December 2015)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: *http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage* For questions or additional information, contact Lori Ashby (410–786–6322).

Facility	Provider No.	Effective date	State
The following facilities are new listings for this quarter			
Community Medical Center Barnabas Health, 99 Highway 37 West Toms River, NJ 08755.	310041	01/07/2016	NJ.
Las Palmas Medical Center, 1801 North Oregon, El Paso, TX 79902	1770536120	01/07/2016	TX.
Sky Ridge Medical Center, 10101 Ridgegate Parkway, Lone Tree, CO 80124	060112	01/04/2016	CO.
McLaren Port Huron, 1221 Pine Grove Port, Huron, MI 48061	1982685384	01/04/2016	MI.
DMC Huron Valley—Sinai Hospital, 1 Williams Carls Drive, Commerce, MI 48382	1922310200	01/04/2016	MI.
Valley Baptist Medical Center—Brownsville, PO Box 450028, 1040 West Jefferson, Brownsville, TX 78520.	450028	03/09/2016	TX.
Manchester Memorial Hospital, 71 Haynes Street, Manchester, CT 06040	1457399198	03/09/2016	CT.
Grand Stand Medical Center, 809 82nd Parkway, Myrtle Beach, SC 29572	1083668669	03/23/2016	SC.
Ben Taub Hospital, 1504 Taub Loop, Houston, TX 77030	450289	03/30/2016	TX.
The following facilities have editorial changes (in bold)			
FROM: Saint Joseph Medical Center, TO: St. Joseph Medical Center, 2500 Bernville Road, Reading, PA 19605.	390096	04/01/2005	PA.
FROM: Helen Ellis Memorial Hospital, TO: Florida Hospital North Pinellas, 1395 South Pinellas Avenue, Tarpon Springs, FL 34689.	100055	01/20/2009	FL.
The following facility has been removed from the listing of approved facilities			
Rockingham Memorial Hospital, 235 Cantrell Avenue, Harrisonburg, VA 22801	490004	06/30/2010	VA.

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 2016)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC–NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC–NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS Web site at *http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961*

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC–NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC–NCDR ICD registry. The entire list of facilities that participate in the ACC–NCDR ICD registry can be found at *www.ncdr.com/webncdr/common*

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our Web site and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: *www.ncdr.com/webncdr/common.* For questions or additional information, contact Marie Casey, BSN, MPH (410–786–7861).

Facility	City	State
The following facilities are new listings for this quarter		
Saint Francis Hospital	Columbus	GA.
CGH Medical Center	Sterling	IL.
Longmont United Hospital	Longmont	CO.
La Paz Regional Hospital	Parker	AZ.
Carlsbad Medical Center	Carlsbad	NM.
Pacific Surgery Center	Costa Mesa	CA.
Memorial Care Outpatient Surgical Center of Long Beach	Long Beach	CA.
Pearland Medical Center (HCA)	Pearland	TX.
Alaska Native Medical Ctr	Anchorage	AK.
Bronx-Lebannon Hospital Center	Bronx	NY.
Kentuckiana Medical Center	Clarksville	IN.
Wheaton Franciscan Healthcare—Franklin, Inc	Milwaukee	WI.
Andalusia Regional Hospital	Andalusia	AL.
Parkway Surgical & Cardiovascular Hospital	Fort Worth	TX.
Bay Area Regional Medical Center	Webster	TX.
Sanford Bemidji Medical Center	Bemidji	MN.
Flushing Hospital Medical Center	Flushing	NY.
Garden Park Medical Center	Gulfport	MS.
Silicon Valley Interventional Surgery Center	Houston	TX.
Surgery Center of Enid, Inc.	Enid	OK.
UPMC East	Monroeville	PA.
Straith Hospital For Special Surgery	Southfield	MI.
Bay Area Hospital	Coos Bay	OR.
Kaiser Permanente Irvine Medical Center	Irvine	CA.
Cohen Children's Medical Center	New Hyde Park	NY.
The following facilities are terminated		
St. Elizabeth Healthcare Florence	Florence	KY.
Lakewood Hospital	Lakewood	OH.
Mease Dunedin Hospital	Dunedin	FL.
Baylor All Saints Medical Center	Dallas	TX.
Regional Medical Center of Acadiana	Lafayette	LA.
CHI Health St. Elizabeth	Lincoln	NE.
Ochsner North Shore Covington	Covington	LA.
Central Carolina (LifePoint)	Sanford	NC.
Mohammed Bin Khalifa Cardiac Centre	Riffa	International.
Rockdale Medical Center	Conyers	GA.

Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2016)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at *http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.* There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin (410–786–7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2016)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at *www.cms.hhs.gov/coverage.* For questions or additional information, contact JoAnna Baldwin (410–786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (January through March 2016)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on positron emission tomography (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at *http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage.* For questions or additional information, contact Stuart Caplan, RN, MAS (410–786–8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2016)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, there were no specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available at *http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage*. For questions or additional information, contact Marie Casey, BSN, MPH (410–786–7861).

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2016)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at *www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage*. For questions or additional information, contact Marie Casey, BSN, MPH (410–786–7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 2016)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at *www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage*. For questions or additional information, contact Sarah Fulton, MPH (410–786–2749).

Addendum XV: FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2016)

There were no FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our Web site at *www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage*. For questions or additional information, contact Stuart Caplan, RN, MAS (410–786–8564).

[FR Doc. 2016–10819 Filed 5–6–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4602]

Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop" that appeared in the **Federal Register** of January 7, 2016. In the document, FDA requested comments on the appropriate level of good manufacturing practices (GMPs) regulation to ensure the safety and effectiveness of air-conduction hearing aid devices. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published January 7, 2016 (81 FR 784). Submit either electronic or written comments by June 30, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–N–4602 for "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, Rm. 2436, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6480, FAX: 301–847–8126, *Srinivas.nandkumar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 7, 2016 (81 FR 784), FDA published a document with a 30-day comment period to request comments on the appropriate level of GMPs regulation to ensure the safety and effectiveness of air-conduction hearing aid devices; the current regulations for air-conduction hearing aids that may hinder innovation, reduce competition, and lead to increased cost and reduced use of these devices by Americans with age-related hearing loss; and the potential exemption of hearing aids from the Quality System Regulation (QSReg,) through use of alternative standards developed in collaboration with key stakeholders and standards development organizations, and recognized by FDA and recordkeeping to ensure product quality. Comments on the "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids" will inform the Agency on an alternative model for quality verification.

The Agency has received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the document on "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids."

FDA has considered the requests and is extending the comment period for the document on "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids" for 30 days, until June 30, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying regulation on these important issues.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10798 Filed 5–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Anesthetic and Analgesic Drug Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Anesthetic and Analgesic Drug Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 1, 2018.

DATES: Authority for the Anesthetic and Analgesic Drug Products Advisory Committee will expire on May 1, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, *AADPAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Issued in 41 CFR 102–3.65 and approval by the Department of Health and Human Services issued in 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Anesthetic and Analgesic Drug Products Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products including analgesics, *e.g.*, abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of anesthesiology, analgesics (such as: abuse deterrent opioids, novel analgesics, and issues related to opioid abuse) epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm094127.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). Since no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: May 3, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–10766 Filed 5–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OMB # 0990–0424–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, Office of Adolescent Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before July 8, 2016.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier OMB # 0990–0424–60D for reference.

Information Collection Request Title: Positive Adolescent Futures (PAF) Study Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Positive Adolescent Futures (PAF) Study will provide information about program design, implementation, and impacts through a rigorous assessment of program impacts and implementation of two programs designed to support expectant and parenting teens. These programs are located in Houston, Texas and throughout the state of California. This revised information collection request includes the 24-month follow-up survey instrument related to the impact study. The data collected from this instrument in the two study sites will provide a detailed understanding of program impacts about two years after youth are enrolled in the study and first have access to the programming offered by each site.

Need and Proposed Use of the Information: The data will serve two main purposes. First, the data will be used to determine program effectiveness by comparing outcomes on repeat pregnancies, sexual risk behaviors, health and well-being, and parenting behaviors between treatment (program) and control youth. Second, the data will be used to understand whether the programs are more effective for some youth than others. The findings from these analyses of program impacts will be of interest to the general public, to policymakers, and to organizations interested in supporting expectant and parenting teens.

Likely Respondents: The 24-month follow-up survey data will be collected through a web-based survey or through telephone interviews with study participants; *i.e.* adolescents randomly assigned to a program for expectant and parenting teens being tested for program effectiveness, or to a control group. The mode of survey administration will primarily be based on the preference of the study participants. The survey will be completed by 1,515 respondents across the two study sites. Clearance is requested for three years.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
24-month follow-up survey of impact study participants	505	1	30/60	252.5
Total				252.5

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–10775 Filed 5–6–16; 8:45 am]

BILLING CODE 4168–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Seek, Test, Treat and Retain For Youth and Young Adults Living with or at High Risk for Acquiring HIV (R01).

Date: May 17, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Residence Inn, Washington DC Downtown, 1199 Vermont Ave. NW., Washington, DC 20005.

Contact Person: Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892–9550, 301–402–2105, *rogersn2@nida.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Identification of Genetic and Genomic Variants by Next-Gen Sequencing in Non-human Animal Models (U01).

Date: June 17, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Jagadeesh S. Rao, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 02892, 301–443–9511, *jrao@nida.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 3, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10779 Filed 5–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850–9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850–9702, Tel. 240–276–5515 or email *ncitechtransfer@mail.nih.gov.* A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Optical trap methods to determine the viscoelastic properties of complex materials, including biological materials

Description of Technology: Optical traps (optical tweezers) have been used to characterize gels and other materials and recently have even shown the ability to characterize the viscoelastic properties of living cells. An optical trap includes a focused laser beam able to trap a small bead at its focus. However, issues of image spatial resolution and limited depth of interrogation have prevented application of an optical trap to measure microrheological (flow of matter) properties in complex (non-uniform) materials, such as multi-cellular systems or living organisms.

Inventors at NIH have developed optical trapping procedures that provide significant improvements in spatial resolution and tissue depth. These improvements are particularly important for examining clinically relevant tissue samples. The viscoelastic measurements obtained using the disclosed systems and methods have a surprisingly high contrast-to-noise ratio compared to prior methods of obtaining viscoelastic measurements for complex materials. The increased contrast-to-noise ratio allows for more sensitive detection of changes in viscoelastic properties across materials than what was possible using prior methods. Thus, the disclosed systems and methods can be used to measure the properties of a wide variety of complex materials (such as biological materials), from 3D tissue culture models to tissue in or from living zebrafish to mammals, such as mice and humans.

Potential Commercial Applications:

- Microrheological measurements can increase knowledge of the cancer microenvironment.
- Diagnosis and/or treatment of a condition or disease associated with tissue/cell remodeling, including tumor state.
- Determine the effectiveness of a particular compound or treatment or regimen (e.g cosmetic products for reducing wrinkles, scarring, etc.).
- Evaluate wound healing.

Value Proposition:

- Increased sensitivity in the detection of changes in viscoelastic properties across materials.
- Improvements in spatial resolution and tissue depth.
- Localized, precise application of force compared to magnetic bead microrheology.
- Greater dynamic range and can probe outside the thermal energy range

compared to passive, thermally driven techniques.

- Selection of multiple probe sites at once allows for increased throughput.
- Automated probe selection reduces assay time.

Development Stage:

Basic

Inventor(s):

Kandice Tanner, Ph.D. (NCI); Benjamin Blehm, Ph.D. (NCI); and Alexus Devine, B.S. (NCI)

Intellectual Property:

HHS Reference No. E–251–2015/0–US–01 US Provisional Application 62/198,554 (HHS Reference No. E–251–2015/0–US–01) filed July 29, 2015 entitled "Optical Trap for Rheological Characterization of Complex Materials".

Publications:

Blehm BH, et al. In vivo tissue has non-linear rheological behavior distinct from 3D biomimetic hydrogels, as determined by AMOTIV microscopy. Biomaterials. 2016 Mar;83:66–78.

Licensing and Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for development of the technology to predict drug treatment based on the mechanical signature and another opportunity for cosmetic applications.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: *john.hewes@nih.gov.*

Dated: May 3, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–10777 Filed 5–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34) and Implementation Cooperative Agreement (U01).

Date: June 1, 2016.

Time: 9:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3G50, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: B. Duane Price, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, RM 3G50, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, 240–669–5074, *pricebd@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: June 2, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3G31 B, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892, (240) 669–5060, *james.snyder@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 3, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10778 Filed 5–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel—NIDCR Clinical Trials Planning Grants.

Date: June 2, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, Room 651, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Crina Frincu, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Blvd., Suite 662, Bethesda, MD 20892, *cfrincu@mail.nih.gov*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 3, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10780 Filed 5–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Injury, Repair, and Remodeling Study Section.

Date: June 1–2, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton Chicago—Magnificent Mile, 300 E Ohio Street, Chicago, IL 60611.

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Learning and Memory Study Section.

Date: June 2, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

Contact Person: Nicholas Gaiano, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892–7844, 301–435–1033, *gaianonr@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: June 2–3, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.

Date: June 2–3, 2016.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@mail.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Development and Disease Study Section.

Date: June 2–3, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott at Metro Center, 775 12th Street NW., Washington, DC 20005.

Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–435–6809, *beheraak@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: June 2–3, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Neurological, Aging and Musculoskeletal Epidemiology Study Section.

Date: June 2–3, 2016.

Time: 8:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Seattle Hotel, 1400 6th Avenue, Seattle, WA 98101.

Contact Person: Heidi B Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–435–1721, *hfriedman@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: An Automated Pipeline for Macromolecular Structure Discovery in Cellular Electron Cryo-Tomography.

Date: June 6, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7760, Bethesda, MD 20892, (301) 404–7419, *rosenzweign@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal, Oral and Skin Sciences AREA review.

Date: June 6, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–451–0996, *ybi@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry A Study Section.

Date: June 7–8, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaylord National Resort and Convention Center, 201 Waterfront Street, National Harbor, MD 20745.

Contact Person: Mike Radtke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301–435–1728, *radtkem@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: June 7–8, 2016.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Cell Biology Integrated Review Group Development—1 Study Section.

Date: June 8, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 3, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10776 Filed 5–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0258]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0049

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the

U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collection of information: 1625–0049, Waterfront Facilities Handling Liquefied Natural Gas (LNG) and Liquefied Hazardous Gas (LHG). Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–0258] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public participation and request for comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek approval of revisions of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2016–0258], and must be received by July 8, 2016.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Waterfront Facilities Handling Liquefied Natural Gas (LNG) and Liquefied Hazardous Gas (LHG).

OMB Control Number: 1625–0049

Summary: Liquefied Natural Gas (LNG) and other Liquefied Hazardous Gases (LHG) present a risk to the public when handled at waterfront facilities. These rules should either prevent accidental releases at waterfront facilities or mitigate their results. They are necessary to promote and verify compliance with safety standards.

Need: Title 33 CFR part 127 prescribe safety standards for the design, construction, equipment, operations, maintenance, personnel training, and fire protection at waterfront facilities handling LNG or LHG.

Forms: None.

Respondents: Owners and operators of waterfront facilities that transfer LNG or LHG.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 6,425 hours to 5,019 hours a year due to a decrease in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: April 29, 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10901 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0262]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0066

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collection of information: 1625–0066, Vessel and Facility Response Plans (Domestic and International), and Additional Response Requirements for Prince William Sound, Alaska. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–0262] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public participation and request for comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://*

www.regulations.gov. Additionally, copies are available from:

COMMANDANT (CG–612), ATTN:
PAPERWORK REDUCTION ACT
MANAGER, U.S. COAST GUARD, 2703
MARTIN LUTHER KING JR AVE. SE.,
STOP 7710, WASHINGTON, DC 20593–
7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek approval of revisions of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2016–0262], and must be received by July 8, 2016.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Vessel and Facility Response Plans (Domestic and International), and Additional Response Requirements for Prince William Sound, Alaska.

OMB Control Number: 1625–0066.

Summary: The Oil Pollution Act of 1990 (OPA 90) required the development of Vessel and Facility Response Plans to minimize the impact of oil spills. OPA 90 also required additional response requirements for Prince William Sound. Shipboard Oil Pollution Emergency Plans and Shipboard Marine Pollution Emergency Plans are required of other vessels to minimize impacts of oil spills.

Need: This information is needed to ensure that vessels and facilities are prepared to respond in event of a spill incident. The information will be reviewed by the Coast Guard to assess the effectiveness of the response plan.

Forms: CG–6083, Application for Approval/Revision of Vessel Pollution Response Plans and Vessel Response Plan (VRP) Express Search Tool.

Respondents: Owners and operators of vessels and facilities.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 136,460 hours to 75,395 hours a year. The decrease in burden is primarily due to a decrease in the estimated annual number of Facility Response Plan (FRP) respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: 29 April 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10899 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–1033]

Collection of Information Under Review by Office of Management and Budget; OMB Control Numbers: 1625–0023

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625–0023, Barge Fleeting Facility Records. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before June 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2015–1033] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov*. Alternatively, you may submit comments to OIRA using one of the following means:

(1) Email: *OIRA-submission@omb.eop.gov*.

(2) *Mail:* OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Fax:* 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov*. Additionally, copies are available from:

COMMANDANT (CG–612), ATTN:
PAPERWORK REDUCTION ACT
MANAGER, U.S. COAST GUARD, 2703
MARTIN LUTHER KING JR AVE SE.,
STOP 7710, WASHINGTON, DC 20593–
7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2015–1033], and must be received by June 8, 2016

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0023.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (81 FR 3148, January 20, 2016) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Barge Fleeting Facility Records.

OMB Control Number: 1625–0023.

Summary: The regulations require the person-in-charge of certain barge fleeting facilities to keep records of twice daily inspections of barge moorings and movements of barges and hazardous cargo in and out of a facility.

Need: Title 33 CFR 165.803 requirements are intended to prevent barges from breaking out of control in the congested Lower Mississippi River waterway system.

Forms: None.

Respondents: Operators of barge fleeting facilities.

Frequency: Daily.

Hour Burden Estimate: The estimated burden has decreased from 50,453 hours to 11,076 hours a year due to a decrease in the estimated annual number of respondents and number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: April 29, 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10897 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0281]

Information Collection Request[s] to Office of Management and Budget; OMB Control Number: 1625-new

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a new collection of information: 1625-new, Maritime Transportation System Recovery Essential Elements of Information. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–0281] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the "Public participation and request for comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov*. Additionally, copies are available from:

COMMANDANT (CG–612), ATTN:
PAPERWORK REDUCTION ACT
MANAGER, U.S. COAST GUARD, 2703
MARTIN LUTHER KING JR. AVE. SE.,
STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of

Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2016–0281], and must be received by July 8, 2016.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Maritime Transportation System Recovery Essential Elements of Information.

OMB Control Number: 1625-new.

Summary: This information collection captures data on facilities, vessels and shared transportation infrastructure prior to a port disruption to be able to characterize the port in its normal fully functioning condition.

Need: 33 U.S.C. 1225, 46 U.S.C. 70103, and 50 U.S.C. 191 require the U.S. Coast Guard to take action to prevent damage to, or the destruction of, bridges, other structures, on or in navigable waters or shore area adjacent; to minimize damage from and respond to a transportation security incident; and to safeguard against destruction of vessels, harbors, ports and waterfront facilities in the United States and all territorial waters during a national emergency. To be prepared to execute these responsibilities, the U.S. Coast Guard needs to establish the normal fully functioning condition of a port prior to a port disruption. Then, following a port disruption, the U.S. Coast Guard may be able to compare the normal port condition to the disrupted port condition, enabling the Marine Transportation System Recovery Unit (MTSRU) to assist in prioritizing recovery efforts, and gauge the effectiveness of the response.

Forms: CG–11410, Marine Transportation System Recovery Essential Elements of Information and CG–11410A, Marine Transportation System Recovery Facility Status.

Respondents: Owners or operators of U.S. waterfront facilities.

Frequency: On occasion.

Hour Burden Estimate: This is a new information collection. The estimated burden is 2,250 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: April 29, 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10898 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–1034]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0052

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0052, Nondestructive Testing of Certain Cargo Tanks on Unmanned Barges. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before June 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2015–1034] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov*. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: OIRA-submission@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Fax:* 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov*. Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR AVE SE., STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2015–1034], and must be received by June 8, 2016.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0052.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (81 FR 3149, January 20, 2016) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Nondestructive Testing of Certain Cargo Tanks on Unmanned Barges.

OMB Control Number: 1625–0052.

Summary: The Coast Guard uses the results of nondestructive testing to evaluate the suitability of older pressure-vessel-type cargo tanks of unmanned barges to remain in service. Such a tank, on an unmanned barge, 30 years old or older is subjected to nondestructive testing once every ten years.

Need: Under title 46 U.S.C. 3703, the Coast Guard is responsible for ensuring safe shipment of liquid dangerous cargoes and has promulgated regulations for certain barges to ensure the meeting of safety standards.

Forms: None.

Respondents: Owners of tank barges.

Frequency: Every 10 years.

Hour Burden Estimate: The estimated burden remains 130 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: April 29, 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10895 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–1097]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0027

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625–0027, Vessel Documentation. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before June 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2015–1097] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) Email: *OIRA-submission@omb.eop.gov.*

(2) Mail: OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) Fax: 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from:
COMMANDANT (CG–612), ATTN:
PAPERWORK REDUCTION ACT
MANAGER, U.S. COAST GUARD, 2703
MARTIN LUTHER KING JR AVE. SE.,
STOP 7710, WASHINGTON, DC 20593–
7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2015–1097], and must be received by June 8, 2016.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0027.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (81 FR 3152, January 20, 2016) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Vessel Documentation.

OMB Control Number: 1625–0027.

Summary: The information collected will be used to establish the eligibility of a vessel to: (a) Be documented as a "vessel of the United States", (b) engage in a particular trade, and/or (c) become the object of a preferred ship's mortgage. The information collected concerns citizenship of owner/applicant and build, tonnage and markings of a vessel.

Need: Title 46 U.S.C. Chapters 121, 123, 125 and 313 requires the documentation of vessels. A Certificate of Documentation (COD) is required for the operation of a vessel in certain trades, serves as evidence of vessel nationality and permits a vessel to be subject to preferred mortgages.

Forms: CG–1258, Application for Initial, Exchange, or Replacement of Certificate of Documentation/Redocumentation; CG–1258, Section A—Additional Vessels; CG–1258, Section H—Additional Owners; CG–1258, Section L—Attachment to Limited Liability Company; CG–1258, Section L—Attachment to Partnership; CG–1258, Section L—Attachment to Joint Venture or Association; CG–1258, Section L—Attachment to Trust Arrangement; CG–1261, Builder's Certification and First Transfer of Title; CG–1270, Certificate of Documentation; CG–1280, Vessel Renewal Notification Application for Renewal; CG–1340, Bill of Sale; CG–1356, Bill of Sale by Government Entity Pursuant to Court Order or Administrative Degree of Forfeiture; CG–4593, Application, Consent, and Approval for Withdrawal of Application for Documentation or Exchange of Certificate of Documentation; CG–5542, Optional Application for Filing; CG–7042, Authorization for Credit Card Transactions; and CG–7043, Abstract of Title/Certified COD Request.

Respondents: Owners/builders of yachts and commercial vessels of at least 5 net tons.

Frequency: Annually.

Hour Burden Estimate: The estimated burden has increased from 67,882 hours to 77,619 hours a year due to an increase in the estimated annual number of responses. With one exception, there is no proposed change to the reporting or recordkeeping requirements of this collection. This ICR is revised to account for the recordkeeping burden of form CG–1270 (Certificate of Documentation (COD)). A COD is issued by the Coast Guard to a vessel owner. We estimate the recordkeeping burden of 3 minutes per response. CODs were issued in the past, but not accounted for under Information Collection 1625–0027. The reporting and recordkeeping requirements, and the methodology for calculating burden, remain unchanged.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: April 29, 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10896 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0261]

Information Collection Request to Office of Management and Budget; OMB

Control Number: 1625–0063

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0063, Marine Occupational Health and Safety Standards for Benzene—46 CFR 197 Subpart C. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 8, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–0261] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public participation and request for comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR AVE. SE., STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2016–0261], and must be received by July 8, 2016

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Marine Occupational Health and Safety Standards for Benzene—46 Code of Federal Regulations 197 Subpart C.

OMB Control Number: 1625–0063.

Summary: To protect marine workers from exposure to toxic Benzene vapor, the Coast Guard implemented Title 46 CFR Subpart C.

Need: This information collection is vital to verifying compliance.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 38,165 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: April 29, 2016.

Thomas P. Michelli,

U.S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–10900 Filed 5–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0093]

Agency Information Collection Activities: Declaration of Owner and Declaration of Consignee When Entry is Made by an Agent

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Declaration of Owner and Declaration of Consignee When Entry is made by an Agent (Forms 3347 and 3347A). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before July 8, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Declaration of Owner and Declaration of Consignee When Entry is made by an Agent.

OMB Number: 1651–0093.

Form Number: CBP Forms 3347 and 3347A.

Abstract: CBP Form 3347, *Declaration of Owner,* is a declaration from the owner of imported merchandise stating that he/she agrees to pay additional or increased duties, therefore releasing the importer of record from paying such duties. This form must be filed within 90 days from the date of entry. CBP Form 3347 is provided for by 19 CFR 24.11 and 141.20.

When entry is made in a consignee's name by an agent who has knowledge of the facts and who is authorized under a proper power of attorney by that consignee, a declaration from the consignee on CBP Form 3347A, *Declaration of Consignee When Entry is Made by an Agent,* shall be filed with the entry summary. If this declaration is filed, then no bond to produce a declaration of the consignee is required. CBP Form 3347A is provided for by 19 CFR 141.19(b)(2).

CBP Forms 3347 and 3347A are authorized by 19 U.S.C. 1485 and are accessible at *http://www.cbp.gov/xp/cgov/toolbox/forms/.*

Action: CBP proposes to extend the expiration date of this information collection with no change to the estimated burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

CBP Form 3347:

Estimated Number of Respondents: 900.

Estimated Number of Responses per Respondent: 6.

Estimated Total Annual Responses: 5,400.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 540.

CBP Form 3347A:

Estimated Number of Respondents: 50.

Estimated Number of Responses per Respondent: 6.

Estimated Total Annual Responses: 300.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 30.

Dated: May 4, 2016.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2016–10810 Filed 5–6–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0082]

Agency Information Collection Activities: African Growth and Opportunity Act Certificate of Origin

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: African Growth and Opportunity Act Certificate of Origin (AGOA). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before July 8, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: African Growth and Opportunity Act Certificate of Origin.

OMB Number: 1651–0082.

Form Number: None.

Abstract: The African Growth and Opportunity Act (AGOA) was adopted by the United States with the enactment of the Trade and Development Act of 2000 (Pub. L. 106–200). The objectives of AGOA are (1) to provide for extension of duty-free treatment under the Generalized System of Preferences (GSP) to import sensitive articles normally excluded from GSP duty treatment, and (2) to provide for the entry of specific textile and apparel articles free of duty and free of any quantitative limits from the countries of sub-Saharan Africa.

For preferential treatment under AGOA, the exporter is required to prepare a certificate of origin and provide it to the importer. The certificate of origin includes information such as contact information for the importer, exporter and producer; the basis for which preferential treatment is claimed; and a description of the imported merchandise. The importers are required to have the certificate in their possession at the time of the claim, and to provide it to Customs and Border Protection (CBP) upon request. The collection of this information is provided for in 19 CFR 10.214, 10.215, and 10.216.

Instructions for complying with this regulation are posted on CBP.gov Web site at: *http://www.cbp.gov/trade/priority-issues.*

Action: CBP proposes to extend the expiration date of this information collection without change to the estimated burden hours or the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 210.

Estimated Number of Annual Responses per Respondent: 107.

Estimated Number of Total Annual Responses: 22,470.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 7,640.

Dated: May 4, 2016.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2016–10809 Filed 5–6–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0016]

Agency Information Collection Activities: Application for Relief Under Former Section 212(c) of the Immigration and Nationality Act, Form I–191; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invite the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until July 8, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0016 in the subject box, the agency name and Docket ID USCIS–2006–0070. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2006–0070;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW, Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments:

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2006–0070 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Relief under Former Section 212(c) of the Immigration and Nationality Act.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–191; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–191 is necessary for USCIS to determine whether the applicant is eligible for discretionary relief under former section 212(c) of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–191 is 600 and the estimated hour burden per response is 1.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 900 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $75,750.

Samantha Deshommes,

Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–10803 Filed 5–6–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2573–15; DHS Docket No. USCIS–2016–0003]

Filipino World War II Veterans Parole Policy

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security (DHS).

ACTION: Notice.

SUMMARY: This notice announces the implementation of U.S. Citizenship and Immigration Services' (USCIS) Filipino World War II Veterans Parole (FWVP) policy. Under this policy, USCIS will

offer certain beneficiaries of approved family-based immigrant visa petitions an opportunity to request a discretionary grant of parole on a case-by-case basis so that they may come to the United States as they wait for their immigrant visa numbers to become available. Among other things, the policy recognizes the extraordinary contributions and sacrifices of Filipino veterans who fought for the United States during World War II. The policy also enhances the ability of such elderly veterans and their spouses to obtain care and support from their family members abroad.

DATES: On or after June 8, 2016, individuals will be able to request parole under the FWVP policy.

FOR FURTHER INFORMATION CONTACT: Maura Nicholson, Deputy Chief, International Operations Division, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Suite 3300, Washington, DC 20529, Telephone 202–272–1892. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background of the FWVP Policy

More than 260,000 Filipino soldiers enlisted to fight for the United States during World War II. Estimates indicate that as many as 26,000 of these brave individuals became U.S. citizens. As U.S. citizens or lawful permanent residents (LPRs), these veterans may petition for certain of their family members to come to the United States. Estimates indicate that there are approximately between 2,000 to 6,000 Filipino American World War II veterans still alive in the United States today, many of whom greatly desire to have their family members in the United States during their final days.[1]

With the exception of "immediate relatives" (*i.e.*, parents, spouses, unmarried children under 21 years of age) of U.S. citizens, *see* Immigration and Nationality Act (INA) sec. 201(b)(2)(A)(i), 8 U.S.C. 1151(b)(2)(A)(i), the number of family-sponsored immigrant visas that are available in any given year is limited by statute. *See* INA secs. 201(a) and (c), 202(a) and 203, 8 U.S.C. 1151(a) and (c), 1152(a) and 1153. These statutory limits have resulted in long waiting periods before family members may join the petitioning U.S. citizens or LPRs in the United States and become LPRs themselves. For certain Filipino American family members, this wait can exceed 20 years.[2]

Recognizing the contributions and sacrifices of Filipino veterans who fought for the United States during World War II and their families, USCIS has decided to implement the FWVP policy. In many cases, paroling these family members may also allow them to provide support and care for elderly veterans or their surviving spouses. Under this policy, USCIS will consider individual requests for parole submitted for certain relatives who are the beneficiaries of approved family-based immigrant visa petitions filed by Filipino veterans or their surviving spouses.[3] Where USCIS determines that exercising such discretion is appropriate, USCIS may approve parole requests for such relatives so that they may wait in the United States until they are able to adjust status under existing immigration laws.[4]

In light of the circumstances described above, among other considerations, USCIS believes that the parole of qualified applicants who establish on a case-by-case basis that they are eligible for consideration under this policy and merit a favorable exercise of discretion would generally yield a "significant public benefit." Additionally, considering the advanced age of World War II Filipino veterans and their spouses, and their increased need for care and companionship, grants of parole under the FWVP policy would often address urgent humanitarian concerns. In all cases, whether to parole a particular individual under this policy is a discretionary determination that will be made on a case-by-case basis. Accordingly, parole applications for individuals who fall within the general criteria but whose cases present overriding adverse factors (*e.g.*, criminal history) would not be approved.

II. Participation in the FWVP Policy and Application Process

Those who may benefit from the FWVP policy are individuals: (1) who are the beneficiaries of Forms I–130, Petition for Alien Relative, including any accompanying or following-to-join spouse and children,[5] who were approved on or before the filing date of the parole request (Form I–131, Application for Travel Document); (2) whose qualifying relationship with the petitioning relative existed on or before May 9, 2016; (3) whose petitioning relative is residing in the United States (or, if deceased, was residing in the United States at the time of death); (4) whose immigrant visas are not authorized for issuance per the Application Final Action Dates chart for family-sponsored preference cases on the Department of State's Visa Bulletin; and (5) whose petitioning relatives have established they are either Filipino World War II veterans or are the surviving spouses of such individuals.

The Filipino veteran's qualifying World War II military service must have previously been recognized by the Department of Defense and must be described in section 405 of the Immigration Act of 1990 (IMMACT'90),[6] as amended by section 112 of Department of Justice Appropriations Act, 1998, which requires an individual to fall within one of three categories:[7]

1. Individuals who are *listed on the final roster* prepared by the recovered Personnel Division of the United States Army of those who served honorably in an active duty status with the Philippine Army during the World War II occupation and liberation of the Philippines;

2. Individuals who are *listed on the final roster* prepared by the Guerilla Affairs Division of the United States Army of those who received recognition as having served honorably in an active duty status within a recognized guerilla unit during the World War II occupation and liberation of the Philippines; or

3. Individuals who served honorably in an active duty status within the Philippine Scouts or within any other component of the United States Armed Forces in the Far East (other than a component described in clauses 1 or 2) at any time during the period beginning

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[1] See *Modernizing and Streamlining our Legal Immigration System for the 21st Century 38 (July 2015), available at https://www.whitehouse.gov/sites/default/files/docs/final_visa_modernization_report1.pdf.*

[2] The January 2016 Visa Bulletin issued by the Department of State indicates that for individuals chargeable to the Philippines, visas may be issued to individuals with priority dates ranging from before August 01, 2014 for family-sponsored second preference category (for spouses and unmarried children of LPRs) to before July 22, 1992 for the family-sponsored fourth preference category (for siblings of U.S. citizens). *See* January 2016 Visa Bulletin, U.S. Department of State, Bureau of Consular Affairs, *available at http://www.travel.state.gov/content/dam/visas/Bulletins/visabulletin_january2016.pdf.*

[3] *See* INA sec. 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A) (permitting parole of certain aliens into the United States, as a matter of discretion and on a case-by-case basis, for urgent humanitarian reasons or significant public benefit); *see also* 8 CFR 212.5(a) and (c)–(e) (discretionary authority for establishing conditions of parole and for terminating parole).

[4] INA sec. 245(a), 8 U.S.C. 1255(a), permits adjustment of status for an alien paroled into the United States. Under 8 CFR 245.1(d)(1)(v), a parolee is considered to be in a lawful status for purposes of INA sec. 245(c)(2) if an individual is seeking adjustment of status as an immediate relative or family-based immigrant.

[5] *See* INA sec. 203(d), 8 U.S.C. 1153(d).

[6] *See* Pub. L. 101–649, 104 Stat. 4978.

[7] *See* Pub. L. 105–119, 111 Stat. 2440.

September 1, 1939, and ending December 31, 1946.

USCIS will review government records to verify that the Filipino veteran's World War II military service was recognized by the Department of Defense. When this documentation is not available, USCIS will issue a Request for Evidence to allow the petitioner to submit evidence establishing the Filipino veteran's military service.

When the petitioning relative in the United States is the Filipino World War II veteran, individuals eligible for parole consideration could include beneficiaries under any family-sponsored preference category. Individuals who qualify as "immediate relatives" under section 201(b)(2)(A)(i) of the INA, 8 U.S.C. 1151(b)(2)(A)(i), however, will not be eligible for parole under this policy because immigrant visas for these individuals are already immediately available. Immediate relatives may seek immigrant visas for travel to the United States immediately upon the approval of immigrant visa petitions filed on their behalf. In situations where the petitioning relative in the United States is the surviving spouse of a Filipino World War II veteran, eligible individuals who may be considered for parole under this policy include only the child, son, or daughter of the surviving spouse who is also the child, son, or daughter of the Filipino World War II veteran.[8]

In cases where the petitioning relative is deceased, eligible individuals described in this paragraph may also seek parole on their own behalf, under this policy, in cases where USCIS has reinstated the approval of Form I–130, Petition for Alien Relative, for humanitarian reasons. If such petition is reinstated, the self-petitioner must establish (1) a qualifying family relationship with the deceased Filipino veteran or spouse (*i.e.* the self-petitioner is a qualifying child, son, daughter, brother or sister of the Filipino World War II veteran); and (2) that the deceased Filipino veteran had qualifying World War II military service, as described above. Again, each of these parole requests will be reviewed on a case-by-case basis to determine whether the petitioner has met the criteria for parole and merits a favorable exercise of discretion.

Seeking parole under the FWVP policy is voluntary.

On or after June 8, 2016, an eligible U.S.-based U.S. citizen or LPR Filipino World War II veteran, or surviving spouse, with an approved Form I–130 may request parole under the FWVP policy on behalf of his or her eligible beneficiary relatives (or, if a self-applicant, on his or her own behalf). An eligible petitioner or self-applicant must file a completed Form I–131, Application for Travel Document, and a completed Form I–134, Affidavit of Support, and submit the required fee(s) or fee waiver request[9] on behalf of each beneficiary he or she wishes to have considered for parole. The veteran, surviving spouse, or self-petitioner must provide documentation of the veteran's qualifying World War II military service as described under section 405 of IMMACT'90, as amended. Detailed instructions on how to request parole under this policy will be included in the Instructions to Form I–131, Application for Travel Document, and on the USCIS Web site at (*www.uscis.gov*). USCIS will reject a Form I–131 that is not properly filed. USCIS strongly encourages individuals seeking to request parole under the FWVP policy to make such requests within 5 years from June 8, 2016 in order for their qualifying family members to be considered under this policy. Following the first four years of the implementation of this policy, USCIS will conduct additional outreach and evaluate whether the volume of actual or potential requests would support maintaining the policy, or whether it should be phased out at the end of 5 years.

USCIS or Department of State consular officers will interview all individuals considered for parole under the FWVP policy to determine whether parole is appropriate on a case-by-case basis.[10] Individuals requesting parole under this policy may also be required to have their biometrics collected. If USCIS favorably exercises its discretion to issue parole under the FWVP policy by approving the Form I–131, USCIS or the Department of State will issue the necessary travel documents to the beneficiary in the location he or she was interviewed. These travel documents generally will enable the beneficiary to travel to a U.S. port-of-entry and request parole from U.S. Customs and Border Protection (CBP) to join his or her family member. Before the beneficiary's parole expires, the beneficiary would be required to (1) seek re-parole; (2) if eligible, apply to adjust status to that of lawful permanent resident or apply and be processed overseas for an immigrant visa; or (3) depart the United States.

If an immigrant visa becomes available to an individual who is not an "immediate relative" while a Form I–131 filed under the FWVP policy is pending, the individual will be considered for parole under this policy, if desired. Alternatively, the beneficiary can choose to pursue immigrant visa processing, which will require payment of associated fees, but will enable the individual to apply for admission to the United States as an immigrant, if found eligible by the Department of State for the immigrant visa and admissible by CBP at a U.S. port of entry.

III. Paperwork Reduction Act (PRA)

Under the PRA, 44 U.S.C. chapter 35, all Departments are required to submit to the Office of Management and Budget (OMB) for review and approval, any new reporting requirements they impose. The USCIS, Application for Travel Document, (Form I–131), has been approved by OMB and assigned OMB control number 1615–0013. USCIS is only revising the Form I–131 Instructions in connection with the implementation of the FWVP policy and this notice. USCIS filed an emergency request with OMB and obtained approval of the changes to the Form I–131 Instructions. More information regarding the annual burden impact resulting from the implementation of this new policy will be provided during the next renewal cycle of the Form I–131. Currently, USCIS estimates that the FWVP policy might result in approximately 6,000 new respondents filing Form I–131s. The current OMB-approved estimated number of respondents filing Form I–131 is 940,671. USCIS believes it has overestimated the number of individuals who will use this form to apply for immigration benefits to the degree that additional respondents who will use it to file a request under the FWVP policy will be covered within the 940,671 estimated.

Additional information about the consideration of parole requests under the FWVP policy will be posted on the USCIS Web site at *www.uscis.gov.*

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[8] *See* INA sec. 101(b)(1) (defining "child"). This definition includes individuals who qualify as step-children, legitimized children, children born out of wedlock and adopted children.

[9] The Director of USCIS has determined that individuals seeking parole under the FWVP policy may request a waiver of the fee for Form I–131, Application for Travel Document. Making the fee waiver available for those applicants who are unable to pay is in the public interest and consistent with other applicable law, consistent with 8 CFR 103.7(d). A fee waiver may be requested by completing Form I–912, Request for Fee Waiver, in accordance with its instructions, and submitting that form with Form I–131.

[10] The Department of State, however, will not make parole determinations.

Dated: May 2, 2016.

León Rodríguez,

Director, U.S. Citizenship and Immigration Services.

[FR Doc. 2016–10750 Filed 5–6–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[FWS–R8–ES–2016–N044; FF08ESMF00–FXES11120800000–156]

Proposed Habitat Conservation Plan/Natural Community Conservation Plan for Western Butte County, California: Environmental Impact Statement

AGENCY: Fish and Wildlife Service, Interior; National Marine Fisheries Service, Commerce.

ACTION: Notice; reopening of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service, are reopening the comment period for our joint request for comments on the Butte Regional Conservation Plan (Plan) and the Draft Environmental Impact Statement/Report (DEIS/R) for Authorization of Incidental Take and Implementation of the Plan. As of January 19, 2016, we have received comments from four organizations and individuals requesting that the comment period be extended. In response to these requests, we are reopening the comment period.

If you previously submitted comments, you need not resubmit them; we have already incorporated them into the public record and will fully consider them in finalizing these documents.

DATES: *Submitting Comments:* To ensure consideration, written comments must be received by June 8, 2016, no later than 5 p.m. Pacific Time.

ADDRESSES: *Submitting Comments:* Please address written comments to one of the following individuals:

1. Mike Thomas, Chief, Conservation Planning Division; or Eric Tattersall, Assistant Field Supervisor, by mail/hand-delivery at U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W–2605, Sacramento, California 95825; or by facsimile to (916) 414–6713. You may telephone (916) 414–6600 to make an appointment during regular business hours to drop off comments at the Sacramento Fish and Wildlife Office.

2. Maria Rea, Assistant Regional Administrator, by mail/hand-delivery at National Oceanic and Atmospheric Administration, West Coast Region, National Marine Fisheries Service, 650 Capitol Mall, Suite 5–100, Sacramento, California 95814; or by facsimile to (916) 930–3629. You may telephone (916) 930–3600 to make an appointment during regular business hours to drop off comments at the National Marine Fisheries Service.

Please send comments related specifically to the California Environmental Quality Act (CEQA) process to the Jon Clark, Executive Director, Butte County Association of Governments, 2580 Sierra Sunrise Terrace, Suite 100, Chico, California 95928. You may also submit comments by facsimile to (530) 879–2444.

FOR FURTHER INFORMATION CONTACT:

(1) Rick Kuyper, Endangered Species Division; Mike Thomas, Chief, Conservation Planning Division; or Eric Tattersall, Deputy Assistant Field Supervisor, at the Sacramento Fish and Wildlife Office address above or at (916) 414–6600 (telephone); or

(2) Gretchen Umlauf, National Marine Fisheries Service, at the address above or at (916) 930–5646 (telephone).

If you use a telecommunications device for the deaf, please call the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: We are reopening the comment period for the Butte Regional Conservation Plan and a DEIS/R for Authorization of Incidental Take and Implementation of the Plan. On November 18, 2015, we opened a 90-day public comment period via a **Federal Register** notice (80 FR 72108). This comment period officially closed on February 16, 2016. Public meetings in Butte County were held in the cities of Chico on January 5, 2016, and Oroville and Gridley on January 6, 2016. As of January 19, 2016, we have received comments from four organizations and individuals requesting that the comment period be extended. In response to requests from the public, we have reopened the comment period (see **DATES**).

Background Information

For background information, see our November 18, 2015, notice (80 FR 72108).

Document Availability

You may obtain copies of the Draft Plan and DEIS/R from any of the individuals in **FOR FURTHER INFORMATION CONTACT**, or from the Sacramento Fish and Wildlife Office Web site at *http://www.fws.gov/sacramento.* Copies of these documents are also available for public inspection, by appointment, during regular business hours, at the Sacramento Fish and Wildlife Office. Additionally, hard-bound copies of the DEIS/R and Draft Plan are available for viewing, or for partial or complete duplication, at the following locations in Chico:

- Butte County Association of Governments, 2580 Sierra Sunrise Terrace, Suite 100;
- Biggs Branch Library, 464A B Street;
- Chico Branch Library, 1108 Sherman Avenue;
- Gridley Branch Library, 299 Spruce Street; and
- Oroville Branch Library, 1820 Mitchell Avenue.

Alexandra Pitts,

Deputy Regional Director, Pacific Southwest Region, U.S. Fish and Wildlife Service, Sacramento, California.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–10863 Filed 5–6–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/A0A501010.999900]

Renewal of Agency Information Collection for Indian Self-Determination and Education Assistance Contracts

AGENCIES: Bureau of Indian Affairs, DOI.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) is seeking comments on the renewal of Office of Management and Budget (OMB) approval for the collection of information for Indian Self-Determination and Education Assistance Contracts, authorized by OMB Control Number 1076–0136. This information collection expires July 31, 2016.

DATES: Submit comments on or before July 8, 2016.

ADDRESSES: You may submit comments on this information collection activities to Ms. Sunshine Jordan, Acting Division Chief, Office of Indian Services—Division of Self-Determination, 1849 C Street NW., MS 4513–MIB, Washington, DC 20240, telephone: (202) 513–7616, email: *Sunshine.Jordan@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Sunshine Jordan, email: *Sunshine.Jordan@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Representatives of the BIA seeks renewal of the approval for information collections conducted under their joint rule, 25 CFR part 900, implementing the Indian Self-Determination and Education Assistance Act (ISDEAA), as amended (25 U.S.C. 450 *et seq.*). The Act requires a joint rule at 25 CFR part 900 to govern how contracts are awarded to Indian Tribes, thereby avoiding the unnecessary burden or confusion associated with two sets of rules and information collection requirements. *See* 25 U.S.C. 450k(a)(2)(A)(ii). The joint rule was developed through negotiated rulemaking with Tribes in 1996 and governs, among other things, what must be included in a Tribe's initial ISDEAA contract proposal to the BIA.

II. Request for Comments

The BIA requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number.

It is BIA's policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personally identifiable information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0136.

Title: Indian Self-Determination and Education Assistance Contracts, 25 CFR part 900.

Brief Description of Collection: An Indian Tribe or Tribal organization is required to submit this information each time that it proposes to contract with BIA under the ISDEAA. Each response may vary in its length. In addition, each subpart of 25 CFR part 900 concerns different parts of the contracting process. For example, subpart C relates to provisions of the contents for the initial contract proposal. The respondents do not incur the burden associated with subpart C when contracts are renewed. Subpart F describes minimum standards for management systems used by Indian Tribes or Tribal organizations under these contracts. Subpart G addresses the negotiability of all reporting and data requirements in the contracts.

Type of Review: Extension without change of currently approved collection.

Respondents: Federally recognized Indian Tribes and Tribal organizations.

Number of Respondents: 550.

Estimated Number of Responses: 5,267.

Estimated Time per Response: Varies from 10 to 50 hours, with an average of 45 hours per response.

Frequency of Response: Each time programs are contracted from the BIA under the ISDEAA.

Obligation To Respond: Response required to obtain or retain a benefit.

Estimated Total Annual Hour Burden: 219,792 hours.

Estimated Total Annual Non-Hour Cost: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2016–10788 Filed 5–6–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[Docket No. ONRR–2012–0003; DS63602000 DR2000000.PX8000 167D0102R2]

U.S. Extractive Industries Transparency Initiative Multi-Stakeholder Group (USEITI MSG) Advisory Committee Meetings Change Notice

AGENCY: Office of the Secretary, Department of the Interior.

ACTION: Notice.

SUMMARY: This notice announces location and date changes to the upcoming meetings of the United States Extractive Industries Transparency Initiative (USEITI) Multi-Stakeholder Group (MSG) Advisory Committee. The location, date, and time for the June 28–29, 2016, meeting has changed and the November 2–3, 2016, meeting has been rescheduled.

DATES AND TIMES: The June 28–29, 2016, meeting has been rescheduled to June 27–28, 2016. The first day of the June meeting, June 27, 2016, will be from 1:00 p.m. to 6:00 p.m., and the second day, June 28, 2016, will be from 9:30 a.m. to 4:00 p.m. Eastern Time. The November 2–3, 2016, meeting has been rescheduled to November 16–17, 2016, from 9:30 a.m. to 4:00 p.m. Eastern Time, unless we indicate otherwise at *www.doi.gov/eiti/faca,* where we will post agendas, meeting logistics, and meeting materials prior to the meeting.

ADDRESSES: The meetings will be held at the U.S. Department of the Interior Stewart Lee Udall Building, 1849 C Street NW., Washington, DC 20240. The June 27–28, 2016, meeting will be held in the South Penthouse, and the November 16–17, 2016, meeting will be held in the North Penthouse. Members of the public may attend in person or view documents and presentations under discussion via WebEx at *http://bit.ly/1cR9W6t* and listen to the proceedings at telephone number 1–888–455–2910 and International toll number 210–839–8953 (passcode: 7741096).

FOR FURTHER INFORMATION CONTACT: Rosita Compton Christian, USEITI Secretariat, 1849 C Street NW., MS–4211, Washington, DC 20240. You may also contact the USEITI Secretariat via email at *useiti@ios.doi.gov,* by phone at 202–208–0272, or by fax at 202–513–0682.

SUPPLEMENTARY INFORMATION: The U.S. Department of the Interior established the USEITI Advisory Committee (Committee) on July 26, 2012, to serve as the initial USEITI multi-stakeholder group. More information about the Committee, including its charter, can be found at *www.doi.gov/eiti/faca.*

Meeting Agendas: At the June 26–27, 2016, meeting agenda will include the MSG discussion of the Independent Administrator (IA) draft Reconciliation Report and the second-phase contextual narrative updates for the 2016 USEITI Report. At the November 16–17, 2016, meeting, the MSG will discuss and approve the final additions to 2016 USEITI Report and the 2017 Annual Workplan. We will post the final agendas and materials for all meetings on the USEITI MSG Web site at *www.doi.gov/eiti/faca.* All Committee meetings are open to the public.

Whenever possible, we encourage those participating by telephone to gather in conference rooms in order to share teleconference lines. Please plan to dial into the meeting and/or log into WebEx at least 10–15 minutes prior to the scheduled start time in order to avoid possible technical difficulties. Individuals with special needs will be accommodated whenever possible. If you require special assistance (such as an interpreter for the hearing impaired), please notify Interior staff in advance of the meeting at 202–208–0272 or via email at *useiti@ios.doi.gov.*

We will post the minutes from these proceedings on the USEITI MSG Web site at *www.doi.gov/eiti/faca,* and they will also be available for public inspection and copying at our office at the Stewart Lee Udall Department of the Interior Building in Washington, DC, by contacting Interior staff at *useiti@ios.doi.gov* or by telephone at 202–208–0272. For more information on USEITI, visit *www.doi.gov/eiti.*

Dated: May 3, 2016.

Paul A. Mussenden,

Deputy Assistant Secretary—Natural Resource Revenue Management.

[FR Doc. 2016–10814 Filed 5–6–16; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WYW 179968]

Public Land Order No. 7852; Withdrawal of Public Land for the Buffalo Bill Dam and Reservoir; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws 32.56 acres of public land from settlement, sale, location, and entry under the general land laws, including the United States mining laws, for a period of 20 years to protect the Buffalo Bill Dam and Reservoir and the recreational facilities near Cody, Wyoming.

DATE: This Public Land Order is effective on May 9, 2016.

FOR FURTHER INFORMATION CONTACT: Janelle Wrigley, Realty Officer, Bureau of Land Management (BLM), Wyoming State Office, 5353 N. Yellowstone Road, Cheyenne, Wyoming 82009, 307–775–6257 or via email at *jwrigley@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This withdrawal protects the completed Buffalo Bill Dam and Reservoir Modification Project, Shoshone Project, Pick-Sloan Missouri Basin Program, Wyoming, as authorized by Public Law 97–293, dated October 12, 1982. The implementing Act for this project provides for 74,000 acre-feet of additional water storage annually for irrigation, municipal, and industrial use; increased hydroelectric power generation; outdoor recreation; fish and wildlife conservation and development; environmental quality; and other purposes. As part of a joint-venture agreement between the Bureau of Reclamation and the State of Wyoming, the land is used by the Wyoming State Parks and Historic Sites and is managed as a State campground. The land is centrally located within this site and major improvements in the form of a campground, roads, playgrounds, restrooms, and picnic and shelter facilities have been constructed.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. Subject to valid existing rights, the following-described public land is hereby withdrawn from settlement, sale, location, and entry under the general land laws, including the United States mining laws, but not from leasing under the mineral leasing laws, to protect the Buffalo Bill Dam and Reservoir and recreation facilities:

Sixth Principal Meridian

T. 52 N., R. 104 W.,
  Sec. 14, lots 10, 11, 26, and 27;
  Sec. 15, lots 21, 22, and 23.

The area described contains 32.56 acres, in Park County.

2. The jurisdiction for all surface uses of these lands is transferred to and exercised by the Bureau of Reclamation, subject to all previously issued leases, licenses, rights of way, and other agreements. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of the land under lease, license, or permit, or governing the disposal of the mineral or vegetative resources other than under the mining laws.

3. This withdrawal will expire 20 years from the effective date of this order, unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be extended.

Dated: April 26, 2016.

Janice M. Schneider,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2016–10862 Filed 5–6–16; 8:45 am]

BILLING CODE 4310–11–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a first amended complaint entitled *Certain Digital Video Receivers and Hardware and Software Components Thereof, DN 3135;* the Commission is soliciting comments on any public interest issues raised by the first amended complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the first amended complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document

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[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a first amended complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Rovi Corporation and Rovi Guides, Inc. on April 25, 2016. The first amended complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital video receivers and hardware and software components thereof. The first amended complaint names as respondents: Comcast Corporation, Philadelphia, PA; Comcast Cable Communications, LLC, Philadelphia, PA; Comcast Cable Communications Management, LLC, Philadelphia, PA; Comcast Business Communications, LLC, Philadelphia, PA; Comcast Holdings Corporation, Philadelphia, PA; Comcast Shared Services, LLC, Chicago, IL; Technicolor SA, France; Technicolor USA, Inc., Indianapolis, IN; Technicolor Connected Home USA LLC, Indianapolis, IN; Pace Ltd., England; Pace Americas, LLC, Boca Raton, FL; Arris International plc, Suwanee, GA; Arris Group Inc., Suwanee, GA; Arris Technology, Inc., Horsham, PA; Arris Enterprises Inc., Suwanee, GA; and Arris Solutions, Inc., Suwanee, GA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the first amended complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3135") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures[4]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

Issued: May 4, 2016.

By order of the Commission.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–10835 Filed 5–6–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–993]

Certain Overflow and Drain Assemblies for Bathtubs and Components Thereof: Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on April 4, 2016, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of WCM Industries, Inc. of Colorado Springs, Colorado. Supplements were filed on April 13, 2016; April 19, 2016; and April 20, 2016. The complaint as supplemented alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain overflow and drain assemblies for bathtubs and components thereof by reason of infringement of certain claims of U.S. Patent No. 8,302,220 ("the '220 patent"); U.S. Patent No. 8,321,970 ("the '970 patent"); U.S. Patent No. 8,584,272 ("the '272 patent"); and U.S. Patent No. 9,200,436 ("the '436 patent"). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

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[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2016).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on May 2, 2016, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain overflow and drain assemblies for bathtubs and components thereof by reason of infringement of one or more of claims 12 and 13 of the '220 patent; claim 1 of the '970 patent; claims 11 and 12 of the '272 patent; and claims 1–16 of the '436 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: WCM Industries, Inc., 2121 Waynoka Road, Colorado Springs, CO 80915.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Bridging Partners Corporation, 4F–1, No. 26, Sec. 3, Ren Ai Road, Taipei 106, Taiwan.

Better Enterprise Co. Ltd., 7F., No. 77, Sec. 4, Nanjing East Road, Taipei 105, Taiwan.

Everflow Industrial Supply Corporation, 16F–1, No. 401, Sec. 1, Chung Shan Road, Changhua, Taiwan.

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: May 3, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–10764 Filed 5–6–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–534–538 and 731–TA–1274–1278 (Final)]

Certain Corrosion-Resistant Steel Products From China, India, Italy, Korea, and Taiwan: Revised Hearing Schedule

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: Effective April 28, 2016.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: Effective January 4, 2016, the Commission established a schedule for the conduct of the final phase of the subject investigations (81 FR 7585, February 12, 2016). The Commission is revising its schedule by changing the time of the hearing. The Commission's hearing will be held at the U.S. International Trade Commission Building at 10:00 a.m. on May 26, 2016. All other aspects of the schedule are unchanged.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Dated: May 3, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–10742 Filed 5–6–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Workforce Innovation and Opportunity Act Common Performance Reporting; Correction

ACTION: Notice; Correction.

SUMMARY: The Department of Labor published a document in the **Federal Register** of April 26, 2016, inviting public comments on the Workforce Innovation and Opportunity Act Common Performance Reporting Information Collection Request (81 FR 24654). The document contained a Web site that has changed in order to review the request and incorrect burden summary information.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email to *DOL_PRA_PUBLIC@dol.gov.*

Correction

In the **Federal Register** of April 26, 2016, in FR Doc. 2016–09637, on page 24654, (81 FR 24654) in the second column, correct the first paragraph of the **ADDRESSES** caption to read:

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201604-1205-008* or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

On page 24655 of the same document, (81 FR 24655) in the second column, correct the 5th paragraph of the **SUPPLEMENTARY INFORMATION** caption to read:

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201604–1205–008.

On page 24655 of the same document, (81 FR 24655) also in the second column, correct the 13th paragraph of the **SUPPLEMENTARY INFORMATION** caption to read:

OMB ICR Reference Number: 201604–1205–008.

On page 24655 of the same document, (81 FR 24655) also in the second column, correct the 15th through 18th paragraphs of the **SUPPLEMENTARY INFORMATION** caption to read:

Total Estimated Number of Respondents: 16,246,121.

Total Estimated Number of Responses: 32,456,962.

Total Estimated Annual Time Burden: 8,372,737 hours.

Total Estimated Other Costs: $26,147,067.

Dated: May 4, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–10806 Filed 5–6–16; 8:45 am]

BILLING CODE 4510–FN–P

LEGAL SERVICES CORPORATION

Extension of Comment Period for Proposed Revisions to the LSC Grant Assurances for Calendar Year 2017 Basic Field Grants

AGENCY: Legal Services Corporation.

ACTION: Notice of extended comment period for proposed changes.

SUMMARY: The Legal Services Corporation ("LSC") is extending the public comment period for the proposed Grant Assurances for calendar year 2017 Basic Field Grants. The proposed revisions affect Grant Assurances 7, 15, 20, and 22. LSC published the original request for comments in the **Federal Register** on April 5, 2016, 81 FR 19640 [FR Doc. 2016–07747]. The proposed LSC Grant Assurances for calendar year 2017 Basic Field Grants, in redline format indicating the proposed changes to the current "LSC 2016 Grant Assurances," are available at *http://grants.lsc.gov/sites/default/files/Grants/ReferenceMaterials/2017-GrantAssurances-Proposed.pdf.* This notice extends the comment period for ten calendar days, from May 5, 2016, to May 16, 2016.

DATES: All comments and recommendations must be received on or before the close of business on May 16, 2016

ADDRESSES: You may submit comments by any of the following methods:

- *Agency Web site: http://www.lsc.gov/contact-us.* Follow the instructions for submitting comments on the Web site.
- *Email: LSCGrantAssurances@lsc.gov.*
- *Fax:* (202) 337–6813.
- *Mail:* Legal Services Corporation, 3333 K Street NW., Washington, DC 20007.

All comments should be addressed to Reginald J. Haley, Office of Program Performance, Legal Services Corporation. Include "2017 LSC Grant Assurances" as the heading or subject line for all comments submitted.

FOR FURTHER INFORMATION CONTACT: Reginald J. Haley, *haleyr@lsc.gov,* (202) 295–1545.

SUPPLEMENTARY INFORMATION: In response to recent requests, LSC is extending the comment period for proposed changes to the Grant Assurances for calendar year 2017 Basic Field Grants.

Grant Assurance 7 requires LSC recipients to provide legal services in accordance with: a) the grant proposal that LSC approved; b) the LSC Performance Criteria; c) the ABA Standards for the Provision of Civil Legal Aid; d) the ABA standards for Programs Providing Civil Pro Bono Legal Services to Persons of Limited Means; and e) any applicable code or rules of professional conduct, responsibility, or ethics. The proposed change clarifies the Grant Assurance and notifies the recipient that LSC's consent is required before the recipient makes significant changes to the delivery system described in the approved grant proposal or grant renewal application.

Grant Assurance 15 requires grantees to notify LSC of: a) an office closing or relocation; b) a change of board chairperson; c) a change of chief executive officer; d) a change in recipient's charter, articles of incorporation, by-laws, or governing body structure; and e) a change in recipient's main email and Web site address. The proposed change updates the instruction for submitting these notifications to LSC.

Grant Assurance 20 requires LSC recipients to provide advance notification to LSC of a proposed merger, consolidation, change in recipient's name, or status as a legal entity. In addition, Grant Assurance 20 directs recipients to LSC's instructions for planning an orderly conclusion of the role and responsibility of an LSC recipient. The proposed change clarifies and adds to the requirements for notifying LSC of a significant change in recipient's status and updates the Web site link to LSC's instructions for planning an orderly conclusion of the role and responsibility of an LSC recipient.

Grant Assurance 22 requires recipients to give recognition and acknowledgement of LSC support and funding by displaying the LSC logo on the recipient's Web site, annual reports, press releases, letterhead, and other similar announcements and documents. The proposed change updates the Web site link to the digital and camera-ready versions of the LSC logo.

Dated: May 3, 2016.

Stefanie K. Davis,

Assistant General Counsel.

[FR Doc. 2016–10770 Filed 5–6–16; 8:45 am]

BILLING CODE 7050–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–033)]

NASA Advisory Council; Science Committee; Planetary Science Subcommittee; Meeting.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Tuesday, June 7, 2016, 1:00 p.m. to 5:00 p.m., Eastern Daylight Time (EDT).

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–2779, or *ann.b.delo@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number 1–877–918–923, passcode 1594921, to participate in this meeting by telephone. A toll number also is available, 1–630–395–0299, passcode 1594921. The WebEx link is *https://nasa.webex.com/;* the meeting number is 995 334 647, password is *PSS@June7.*

The agenda for the meeting includes the following topics:

- Planetary Science Division Update
- Planetary Science Division Research and Analysis Program Update

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–10811 Filed 5–6–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

NOTICE: (16–032)

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Frances Teel, National Aeronautics and Space Administration, 300 E Streets SW., Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA Clearance Officer, NASA Headquarters, 300 E Street SW., JF000, Washington, DC 20546, *Frances.C.Teel@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information supports the National Aeronautics and Space Act of 1958, as amended, to create opportunities to improve processes associated with the evaluation and selection of individuals to participate in the NASA Astronaut Candidate Selection Program. The NASA Astronaut Selection Office (ASO) located at the Lyndon B. Johnson Space Center (JSC) in Houston, Texas is responsible for selecting astronauts for the various United States Space Exploration programs. In evaluating an applicant for the Astronaut Candidate Program, it is important that the ASO have the benefit of qualitative and quantitative information and recommendations from persons who have been directly associated with the applicant over the course of their career.

This information will be used by the NASA ASO and Human Resources (HR) personnel, during the candidate selection process (approx. 2 year duration), to gain insight into the candidates' work ethic and professionalism as demonstrated in previous related employment activities. Respondents may include the astronaut candidate's previous employer(s)/direct-reporting manager, as well as co-workers and other references provided by the candidate.

II. Method of Collection

Electronic and optionally by paper.

III. Data

Title: NASA Astronaut Candidate Selection (ASCAN) Qualifications Inquiry.

OMB Number: 2700–0156.

Type of review: Extension of a currently approved information collection.

Affected Public: Individuals.

Estimated Number of Respondents: 2,000.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 667.

Estimated Total Annual Cost: $50,905.00.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2016–10812 Filed 5–6–16; 8:45 am]

BILLING CODE 7510–16–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the addition of an agenda item in the plenary open session of the National Science Board meetings on May 6, 2016, as shown below. The original notice appeared in the **Federal Register** on Friday, April 29, 2016 at 81 FR 25721–22.

AMENDED AGENDA:

Plenary Board

Open session: 1:00–2:30 p.m.

- Approval of open plenary minutes for February, 2016
- NSB Chair's opening remarks
- Introduction of the NSF "LIGO Team"
- NSF Director's remarks
- Review and approval of annual Executive Committee report
- OIG Semiannual report (ADDED)
- Open committee reports
- Discharge NPP
- Presentations to outgoing Board members
- NSB Chair's closing remarks

UPDATES: Please refer to the National Science Board Web site for additional information. Meeting information and schedule updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp.*

AGENCY CONTACT: Ron Campbell, *jrcampbe@nsf.gov,* 703–292–7000.

Dated: May 5, 2016.

Suzanne Plimpton,

Management Analyst, National Science Foundation.

[FR Doc. 2016–10991 Filed 5–5–16; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Comment Request: National Science Foundation Proposal—Large Facilities Manual

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request renewed clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on the NSF Large Facilities Manual (LFM) and the accompanying Large Facilities Financial Data Collection Tool. The primary purpose of this revision is to implement financial management policy and requirements as well as to update and clarify existing content. The draft versions of the NSF LFM and the accompanying Large Facilities Financial Data Collection Tool are available on the NSF Web site at: *http://www.nsf.gov/bfa/lfo/lfo_documents.jsp.*

To facilitate review, a Change Log with brief comment explanations of the changes is provided in the manual. NSF is particularly interested in public comment on the financial management changes identified in the LFM and on the Large Facilities Financial Data Collection Tool for use in incurred cost reporting. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

In addition to the type of comments identified above, comments are also invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be received by July 8, 2016 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 1265, Arlington, VA 22230, or by email to *splimpto@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton on (703) 292–7556 or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: "Large Facilities Manual"

OMB Approval Number: 3145–0239.

Expiration Date of Approval: 6/30/2018.

Type of Request: Intent to seek approval to extend with revision an information collection for three years.

Proposed Project: The National Science Foundation Act of 1950 (Pub. L. 81–507) set forth NSF's mission and purpose:

"To promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense. * * *"

The Act authorized and directed NSF to initiate and support:

- Basic scientific research and research fundamental to the engineering process;
- Programs to strengthen scientific and engineering research potential;
- Science and engineering education programs at all levels and in all the various fields of science and engineering;
- Programs that provide a source of information for policy formulation; and
- Other activities to promote these ends.

Among Federal agencies, NSF is a leader in providing the academic community with advanced instrumentation needed to conduct state-of-the-art research and to educate the next generation of scientists, engineers and technical workers. The knowledge generated by these tools sustains U.S. leadership in science and engineering (S&E) to drive the U.S. economy and secure the future. NSF's responsibility is to ensure that the research and education communities have access to these resources, and to provide the support needed to utilize them optimally, and implement timely upgrades.

The scale of advanced instrumentation ranges from small research instruments to shared resources or facilities that can be used by entire communities. The demand for such instrumentation is very high, and is growing rapidly, along with the pace of discovery. For large facilities and shared infrastructure, the need is particularly high. This trend is expected to accelerate in the future as increasing numbers of researchers and educators rely on such large facilities, instruments, and databases to provide the reach to make the next intellectual leaps.

NSF currently provides support for facility construction from two accounts:

the Major Research Equipment and Facility Construction (MREFC) account, and the Research and Related Activities (R&RA) account. The MREFC account, established in FY 1995, is a separate budget line item that provides an agency-wide mechanism, permitting directorates to undertake large facility projects that exceed 10% of the Directorate's annual budget; or roughly $100M or greater. Smaller projects continue to be supported from the R&RA Account.

Facilities are defined as shared-use infrastructure, instrumentation and equipment that are accessible to a broad community of researchers and/or educators. Facilities may be centralized or may consist of distributed installations. They may incorporate large-scale networking or computational infrastructure, multi-user instruments or networks of such instruments, or other infrastructure, instrumentation and equipment having a major impact on a broad segment of a scientific or engineering discipline. Historically, awards have been made for such diverse projects as accelerators, telescopes, research vessels and aircraft, and geographically distributed but networked sensors and instrumentation.

The growth and diversification of large facility projects require that NSF remain attentive to the ever-changing issues and challenges inherent in their planning, construction, operation, management and oversight. Most importantly, dedicated, competent NSF and awardee staff are needed to manage and oversee these projects; giving the attention and oversight that good practice dictates and that proper accountability to taxpayers and Congress demands. To this end, there is also a need for consistent, documented requirements and procedures to be understood and used by NSF program managers and awardees for all such large projects.

Use of the Information: Facilities are an essential part of the science and engineering enterprise, and supporting them is one major responsibility of the National Science Foundation (NSF). NSF makes awards to external entities—primarily universities, consortia of universities or non-profit organizations—to undertake construction, management and operation of facilities. Such awards frequently take the form of cooperative agreements. NSF does not directly construct or operate the facilities it supports. However, NSF retains responsibility for overseeing their development, management and successful performance. The Large Facilities Manual is intended to:

- Provide step-by-step guidance for NSF staff and awardees to carry out effective project planning, management and oversight of large facilities while considering the varying requirements of a diverse portfolio;
- Clearly state the policies, processes and procedures pertinent at each stage of a facility's life cycle from development through construction, operations, and termination; and
- Document and disseminate "best practices" identified over time so that NSF and awardees can carry out their responsibilities more effectively.

This version of the Large Facilities Manual up-dates sections related to contingency policy, cost estimating requirements, and cost incurred audits. As part of the implementation of incurred cost reporting, a Large Facilities Financial Data Collection Tool is referenced in the Manual and included in the request for comment. This version also reflects revisions to improve readability and facilitate period revision. The Manual does not replace existing formal procedures required for all NSF awards, which are described in the *Grant Proposal Guide* and *The Award and Administration Guide.* Instead, it draws upon and supplements them for the purpose of providing detailed guidance regarding NSF management and oversight of facilities projects. All facilities projects require merit and technical review, as well as approval of certain deliverables. The level of review and approval varies substantially from standard grants, as does the level of oversight needed to ensure appropriate and proper accountability for federal funds. The requirements, recommended procedures and best practices presented in the Manual apply to any facility significant enough to require close and substantial interaction with the Foundation and the National Science Board.

This Manual will be updated periodically to reflect changes in requirements, policies and/or procedures. Award Recipients are expected to monitor and adopt the requirements and best practices included in the Manual which are aimed at improving management and oversight of large facilities projects and at enabling the most efficient and cost-effective delivery of tools to the research and education communities.

The submission of proposals and subsequent project documentation to the Foundation related to the development, construction and operations of Large Facilities is part of the collection of information. This information is used to help NSF fulfill this responsibility in supporting merit-based research and education projects in all the scientific and engineering disciplines. The Foundation also has a continuing commitment to provide oversight on facilities development and construction which must be balanced against monitoring its information collection so as to identify and address any excessive reporting burdens.

NSF has approximately twenty-two (22) Large Facilities in various stages of development, construction, operations and termination. One to two (1 to 2) new awards are made approximately every five (5) years based on science community infrastructure needs and availability of funding. Of the twenty-two large facilities, there are approximately eight (8) facilities annually that are either in development or construction. These stages require the highest level of reporting and management documentation per the Large Facilities Manual.

Burden to the Public: The Foundation estimates that an average of three (3) Full Time Equivalents (FTE's) are necessary for each facility project in development or construction (Total Project Cost of $200–$500M) to respond to NSF routine reporting and project management documentation requirements on an annual basis; or 6240 hours per year. The Foundation estimates an average of one (1) FTE for a facility in operations; or 2080 hours per year. Assuming an average of eight (8) facilities in construction and the balance in operations, this equates to roughly 80,000 public burden hours annually.

Dated: May 3, 2016.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2016–10793 Filed 5–6–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Digital I&C; Cancellation of the May 17, 2016, ACRS Subcommittee Meeting

The ACRS Subcommittee meeting on Digital I&C scheduled for May 17, 2016, 1:00 p.m. until 5:00 p.m., has been cancelled.

The notice of this meeting was previously published in the **Federal Register** on Wednesday, April 27, 2016, (81 FR 24894).

Information regarding this meeting can be obtained by contacting Christina

Antonescu, Designated Federal Official (DFO) (Telephone 301–415–6792 or Email: *Christina.Antonescu@nrc.gov*) between 7:30 a.m. and 5:15 p.m. (EST)).

Dated: April 28, 2018.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–10818 Filed 5–6–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on T–H Phenomena; Notice of Meeting

The ACRS Subcommittees on T–H Phenomenon and Metallurgy & Reactor Fuels will hold a meeting on May 17, 2016, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, May 17, 2016—1:00 p.m. until 5:00 p.m.

The Subcommittee will review the final draft of Regulatory Guide 1.20, "Comprehensive Vibration Assessment Program for Reactor Internals during Preoperation and Startup." The Subcommittee will hear presentations by and hold discussions with the NRC staff regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Derek Widmayer (Telephone 301–415–5375 or Email: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the

DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015, (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: April 28, 2016.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–10815 Filed 5–6–16; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Administrative Appeals

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation ("PBGC") is requesting that the Office of Management and Budget ("OMB") extend approval, under the Paperwork Reduction Act, of a collection of information under its regulation on Rules for Administrative Review of Agency Decisions. This notice informs the public of PBGC's request and solicits public comment on the collection of information.

DATES: Comments should be submitted by June 8, 2016.

ADDRESSES: Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, via electronic mail at *OIRA_DOCKET@omb.eop.gov* or by fax to (202) 395–6974.

Copies of the collection of information may also be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel of PBGC at the above address or by visiting the Disclosure Division or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.) PBGC's regulation on Administrative Appeals may be accessed on PBGC's Web site at *www.pbgc.gov*.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Deputy Assistant General Counsel for Regulatory Affairs, or Donald McCabe, Attorney, Regulatory Affairs Group, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026, 202–326–4400. (For TTY and TDD, call 800–877–8339 and request connection to 202–326–4400).

SUPPLEMENTARY INFORMATION: PBGC's regulation on Rules for Administrative Review of Agency Decisions (29 CFR part 4003) prescribes rules governing the issuance of initial determinations by PBGC and the procedures for requesting and obtaining administrative review of initial determinations. Certain types of initial determinations are subject to administrative appeals, which are covered in subpart D of the regulation. Subpart D prescribes rules on who may file appeals, when and where to file appeals, contents of appeals, and other matters relating to appeals.

Most appeals filed with PBGC are filed by individuals (participants, beneficiaries, and alternate payees) in connection with benefit entitlement or amounts. A small number of appeals are filed by employers in connection with other matters, such as plan coverage under ERISA section 4021 or employer liability under ERISA sections 4062(b)(1), 4063, or 4064. Appeals may be filed by hand, mail, commercial delivery service, fax or email. For appeals of benefit determinations, PBGC has optional forms for filing appeals and requests for extensions of time to appeal.

OMB has approved the administrative appeals collection of information under control number 1212–0061 through May 31, 2016. PBGC is requesting that OMB extend approval of this collection of information for three years without change. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that an average of 900 appellants per year will respond to this collection of information. PBGC further estimates that the average annual burden of this collection of information is about forty-five minutes and $52 per appellant, with an average total annual burden of 643 hours and $46,680.

Issued in Washington, DC, this 2 day of May 2016.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2016–10813 Filed 5–6–16; 8:45 am]

BILLING CODE 7709–02–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77758; File No. SR–CBOE–2016–040]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

May 3, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 21, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Fees Schedule to update references to quoting bandwidth. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule, effective April 21, 2016.

The Fees Schedule currently sets forth the quoting bandwidth allowance for a Market-Maker Trading Permit. The bandwidth allowance is referenced as a maximum number of quotes over the course of the trading day (currently 35,640,000). The Exchange notes however, that the current reference applies to the Regular Trading Hours session ("RTH") only. In order to avoid confusion and maintain clarity and transparency in the rules, the Exchange proposes to add a reference to the quoting bandwidth allowance for an Extended Trading Hours[5] ("ETH") Market-Maker Trading Permit (*i.e.*, 37,500,000 quotes over the course of the ETH session).[6] The Exchanges notes that ETH bandwidth applies to all ETH Market-Maker Trading Permits and all ETH Quoting and Order Entry Bandwidth Packets. The Exchange also notes that the trading hours for RTH and ETH differ and as such, an ETH Market-Maker Trading Permit is equivalent to a different maximum number of quotes over the course of the trading session.[7]

The Exchange next proposes to update the bandwidth currently set forth in Fees Schedule. The Fees Schedule currently states that the quoting bandwidth allowance for a Market-Maker Trading Permit is equivalent to a maximum of 35,640,000 quotes over the course of a trading day. The Exchange proposes to clarify that the stated quoting bandwidth reflects the maximum number of quotes over the course of a trading "session" instead of trading "day." Particularly, RTH and ETH are separate trading sessions that are part of the same trading day. As such, the current expression of RTH bandwidth as quotes over the course of a trading "day" is inaccurate. Next, the Exchange notes that it increased quoting bandwidth allowance, effective April 18, 2016. The Exchange therefore seeks to make a corresponding amendment to the Fees Schedule. Specifically, the Exchange proposes to update the reference to the number of maximum quotes from 35,640,000 to 40,500,000. The Exchange notes that the increase of quoting bandwidth allowance applies to all RTH Market-Maker Trading Permits and all RTH Quoting and Order Entry Bandwidth Packets.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)[9] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that adding a reference to the quoting bandwidth allowance during ETH avoids potential confusion and maintains transparency in the Fees Schedule, thereby removing impediments to and perfecting the mechanism of a free open market and a national market system, and, in general, protecting investors and the public interest. Similarly, as RTH and ETH are separate trading sessions (but part of the same trading day), the current reference to the RTH bandwidth as a maximum number of quotes over the course of a trading "day" is no longer accurate and as such, the Exchange believes replacing "trading day" with "trading session" eliminates incorrect terminology and avoids potential confusion.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] Extended Trading Hours are from 2:00 a.m. Central time ("CT") to 8:15 a.m. (CT) on Monday through Friday.

[6] The Exchange notes that prior to April 18, 2016, the maximum bandwidth quoting allowance during ETH was 33,000,000 quotes over the course of the ETH session.

[7] The rate per second(s) for quoting bandwidth is (and has always been) the same for both the RTH and ETH sessions. Because the ETH trading session is shorter than the RTH trading session, the stated number of quotes over the course of a trading session is less for ETH than RTH.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *Id.*

The Exchange believes that amending the Fees Schedule to accurately reflect the increase in quoting bandwidth allowance, alleviates confusion, thereby removing impediments to and perfecting the mechanism of a free open market and a national market system, and, in general, protecting investors and the public interest. The Exchange also notes that increasing quoting bandwidth helps ensure that Market-Makers have an adequate capacity and ability to continue to make active markets, which also removes impediments to and perfects the mechanism of a free open market and a national market system, and, in general, protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change applies to all Market-Makers and is merely updating the Fees Schedule to accurately reflect an increase in quoting bandwidth, update outdated terminology, and reflect what the maximum bandwidth is for ETH. The Exchange believes that the proposed rule change will not cause an unnecessary burden on intermarket competition because it only applies to trading on CBOE. To the extent that the proposed changes make CBOE a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become CBOE market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission,[11] the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that without a waiver of the operative delay, the Fees Schedule would reflect an outdated bandwidth amount, of only one trading session, which could cause potential confusion to TPHs. The Commission believes that it is consistent with the protection of investors and the public interest to waive the 30-day operative delay so the Exchange's Fees Schedule may immediately reflect the correct bandwidth fees. For this reason, the Commission designates the proposed rule change to be operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2016–040 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–040. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–040 and should be submitted on or before May 31, 2016.

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[11] The Exchange has fulfilled this requirement.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10758 Filed 5–6–16; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Council on Underserved Communities Advisory Board

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory Committee meetings.

SUMMARY: The SBA is issuing this notice to announce the location, date, time and agenda for the initial meeting of the Council on Underserved Communities (CUC) Advisory Board.

DATES: The meeting will be held on Tuesday, May 24th at 1:00 pm EST.

ADDRESSES: These meeting will be held at the U.S. Small Business Administration, in the Administrator's Large Conference Room, located at 409 3rd St. SW., Suite 7000, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), SBA announces the meeting of the Council on Underserved Communities Advisory Board. This Board provides advice and counsel to the SBA Administrator and Associate Administrator. CUC members will examine the obstacles facing small businesses in underserved communities and recommend to SBA policy and programmatic changes to help strengthen SBA's programs and services to these communities.

The purpose of this meeting is to discuss following issues pertaining to the CUC Advisory Board.:

—Provide information on key SBA programs
—Board Assignments
—Determine the 2016 CUC Agenda

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public however advance notice of attendance is requested. Anyone wishing to be a listening participant must contact Amadi Anene by phone or email. His contact information is Amadi Anene, Senior Advisor to the Administrator, 409 Third Street SW., Washington, DC 20416, Phone, 202–205–0067 or email, *amadi.anene@sba.gov.*

Additionally, if you need accommodations because of a disability or require additional information, please contact Amadi Anene at the information above.

Miguel L' Heureux,

White House Liaison.

[FR Doc. 2016–10546 Filed 5–6–16; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9552]

Notice of Information Collection Under OMB Emergency Review: Employee Self Certification and Ability To Perform In Emergencies (ESCAPE) Program

ACTION: Notice of request for emergency OMB approval and public comment.

SUMMARY: The Department of State has submitted the information collection request described below to the Office of Management and Budget (OMB) for review and approval in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995 (5 CFR 1320.13). The purpose of this notice is to allow for public comment from all interested individuals and organizations. Emergency review and approval of this collection has been requested from OMB by May 23, 2016. If granted, the emergency approval is only valid for 180 days. The Department plans to follow this emergency request with a submission for a 3 year approval through OMB's normal PRA clearance process (5 CFR 1320.10).

DATES: All public comments must be received by May 16, 2016.

ADDRESSES: Direct any comments on this emergency request to both the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB) and to the Office of Medical Services, U.S. Department of State. All public comments must be received by May 16, 2016.

You may submit comments to OMB by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

You may submit comments to the Office of Medical Services, U.S. Department of State by the following methods:

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering "Docket Number: DOS–2016–0026" in the Search field. Then click the "Comment Now" button and complete the comment form.
- *Email:* Catherine M. Kazmin at *kazmincm@state.gov.* You must include Emergency Submission Comment on "Employee Self Certification And Ability To Perform In Emergencies" (ESCAPE) Program in the subject line of your message.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents to Catherine M. Kazmin who may be reached on 703–875–5413 or at *kazmincm@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Employee Self Certification And Ability To Perform In Emergencies (ESCAPE) Program.
- *OMB Control Number:* None.
- *Type of Request:* Emergency Review.
- *Originating Office:* Office of Medical Services (MED).
- *Form Number:* DS–6570.
- *Respondents:* Non-federal individuals being considered for contracted assignments at ESCAPE-designated posts.
- *Estimated Number of Respondents:* 200 annually.
- *Estimated Number of Responses:* 200 annually.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 100 hours annually.
- *Frequency:* One time per deployment to ESCAPE post.
- *Obligation to respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden of this proposed collection, including the validity of the methodology and assumptions used.

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[17] 17 CFR 200.30–3(a)(12).

- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review

Abstract of proposed collection:

The goal of the "Employee Self Certification And Ability To Perform In Emergencies" (ESCAPE) program is to ensure that non-federal individuals who are being considered for a contracted position at a designated post are capable of the unique, potentially challenging and life threatening conditions at ESCAPE posts. These individuals are required to review with a medical provider the pre-deployment acknowledgement form (DS–6570) and then affirm that they understand the physical rigors and security conditions at these posts and can perform any specified emergency functions. Medical information is collected from medical providers and respondents during this review. The Department of State is requesting an emergency review and approval of this Information Collection so non-federal individuals who will be selected for assignments in June, 2016 can provide completed pre-deployment medical information. This Collection is allowed under the Foreign Service Act of 1980 (22 U.S.C. 3901) and the Basic Authorities Act of 1956 (22 U.S.C. 2651).

Methodology:

Information will be collected using a form (DS–6570) during a medical review between a non-federal individual and his/her medical provider. The individual will submit the completed form, signed by both the individual and provider, to the Office of Medical Services at the U.S. Department of State.

Dated: May 4, 2016.

Ernest E. Davis,

Director of Medical Clearances, Office of Medical Services, Department of State.

[FR Doc. 2016–10834 Filed 5–6–16; 8:45 am]

BILLING CODE 4710–36–P

DEPARTMENT OF STATE

[Public Notice: 9551]

In the Matter of the Designation of Musa Abu Dawud, aka Moussa Abu Daoud, aka Moussa Bourahla, aka Abou Daoud, aka Bourahla Moussa, as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Moussa Abu Dawud, also known as Moussa Abu Daoud, also known as Moussa Bourahla, also known as Abou Daoud, also known as Bourahla Moussa committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States. Consistent with the determination in section 10 of Executive Order 13224 that "prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously," I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–10844 Filed 5–6–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9550]

Bureau of Political-Military Affairs; Modification of Statutory Debarment Imposed Pursuant to Section 127.7(c) of the International Traffic in Arms Regulations—Rocky Mountain Instrument Company

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State will consider license applications for the indirect participation of Rocky Mountain Instrument Company ("RMI") in certain transactions subject to the Arms Export Control Act (AECA) (22 U.S.C 2778) without the submission of a transaction exception request as an element of the application.

DATES: This notice is effective on May 9, 2016.

FOR FURTHER INFORMATION CONTACT: Sue Gainor, Director, Office of Defense Trade Controls Compliance, Bureau of Political-Military Affairs, U.S. Department of State (202) 632–2785.

SUPPLEMENTARY INFORMATION: On September 8, 2010, the Department notified the public of a statutory debarment imposed on RMI pursuant to ITAR § 127.7(c) related to RMI's criminal conviction, 75 FR 54692. The notice provided that RMI is "prohibited from participating directly or indirectly in the export of defense articles, including technical data, or in the furnishing of defense services for which a license or other approval is required." Further, the notice provided that:

> Exceptions, also known as transaction exceptions, may be made to this debarment determination on a case-by-case basis at the discretion of the Assistant Secretary of State for Political-Military Affairs, after consulting with the appropriate U.S. agencies. However, such an exception would be granted only after a full review of all circumstances, paying particular attention to the following factors: Whether an exception is warranted by overriding U.S. foreign policy or national security interests; whether an exception would further law enforcement concerns that are consistent with the foreign policy or national security interests of the United States; or whether other compelling circumstances exist that are consistent with the foreign policy or national security interests of the United States, and that do not conflict with law enforcement concerns. Even if exceptions are granted, the debarment continues until subsequent reinstatement.

Notwithstanding the prohibition on indirect participation referenced in the original notice of statutory debarment, and in conformance with the stated policy and procedures regarding transaction exceptions, based on overriding national security and foreign policy concerns and after a thorough review of the circumstances surrounding the conviction and a finding that appropriate steps have been taken to mitigate law enforcement concerns, the Under Secretary for Arms Control and International Security has determined to approve specific exceptions from the debarment of RMI, available to persons other than RMI but excluding persons acting for or on behalf of RMI in contravention of ITAR § 127.1(d), for the following categories of authorization requests:

1. Applications submitted by persons other than RMI for the export or

temporary import of defense articles manufactured by RMI (*i.e.*, where RMI is identified as a Source or Manufacturer);

2. Application submitted by persons other than RMI for the export or temporary import of defense articles manufactured by persons other than RMI which incorporate a defense article manufactured by RMI as a component, accessory, attachment, part, firmware, software, or system;

3. The use of other approvals (*see* ITAR § 120.20) by persons other than RMI for the export or temporary import of defense articles described in categories one (1) and two (2) above; and

4. Applications submitted by persons other than RMI for agreements identified in ITAR Part 124 in which RMI is identified as a U.S. signatory to the agreement.

All requests for authorizations, or use of exemptions, involving RMI that fall within the scope of the specific categories above will be reviewed and action taken by the Directorate of Defense Trade Controls in the ordinary course of business and do not require the submission of a separate transaction exception request, but should include reference to, or a copy of, this notice. Including an explanation of how the proposed transaction falls within the scope of an exception category above will facilitate review of the request.

All requests for authorizations involving RMI that do not fall within the scope of the specific categories above must be preceded by the approval of a transaction exception request by the Department. The decision to grant a transaction exception will be made on a case-by-case basis after a full review of all circumstances.

This notice does not provide notice of reinstatement of export privileges for RMI pursuant to the statutory requirements of AECA Sec. 38(g)(4) (22 U.S.C. 2778), nor does this notice provide notice of rescission of the imposition of statutory debarment of RMI pursuant to ITAR § 127.7(c). As required by the statute, the Department will not consider applications from RMI unless accompanied by a specific transaction exception request. Any determination by the Department regarding reinstatement of export privileges for RMI or rescission of the imposition of statutory debarment of RMI will be made in accordance with statutory and regulatory requirements and will be the subject of a separate notice.

Dated: April 25, 2016.

Rose E. Gottemoeller,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2016–10843 Filed 5–6–16; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Public Notice: 9549]

Notice of Availability of the Draft Environmental Assessment and Preliminary Finding of No Significant Impact for the NuStar Burgos Pipelines Presidential Permit Applications Review, Hidalgo County, Texas

AGENCY: Department of State.

ACTION: Notice of availability, solicitation of comments.

SUMMARY: The U.S. Department of State (Department) announces availability for public review and comment of the *Draft Environmental Assessment* (Draft EA) and the *Preliminary Finding of No Significant Impact for the NuStar Burgos Pipelines Presidential Permit Applications Review* (Preliminary FONSI). These documents evaluate the potential environmental impacts of issuing Presidential Permits to NuStar Logistics, L.P. (NuStar) to authorize in Hidalgo County, Texas: The construction, connection, operation, and maintenance of a proposed new NuStar Burgos pipeline (New Burgos Pipeline); a proposed change in petroleum products for an existing Burgos pipeline (Existing Burgos Pipeline), for which a Presidential Permit was issued in 2006; and a name change of the owner and operator of the Existing Burgos Pipeline. The Draft EA and Preliminary FONSI were prepared consistent with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. Sec. 4321, *et seq.*), the regulations of the Council on Environmental Quality (CEQ) (40 CFR 1500–1508), and the Department's implementing regulations (22 CFR part 161).

DATES: The Department invites the public, governmental agencies, tribal governments, and all other interested parties to provide comments on the Draft EA and Preliminary FONSI during the 30-day public comment period. The public comment period starts on May 9, 2016, with the publication of this **Federal Register** Notice and will end June 8, 2016.

All comments received during the review period may be made public, no matter how initially submitted. Comments are not private and will not be edited to remove identifying or contact information. Commenters are cautioned against including any information that they would not want publicly disclosed. Any party soliciting or aggregating comments from other persons is further requested to direct those persons not to include any identifying or contact information, or information they would not want publicly disclosed, in their comments.

ADDRESSES: Comments on the Draft EA and Preliminary FONSI may be submitted at *www.regulations.gov* by entering the title of this Notice into the search field and following the prompts. Comments may also be submitted by mail, addressed to: Burgos Project Manager, Office of Environmental Quality and Transboundary Issues (OES/EQT): Suite 2726, U.S. Department of State, 2201 C Street NW., Washington, DC 20520. All comments from agencies or organizations should indicate a contact person for the agency or organization.

FOR FURTHER INFORMATION CONTACT: Project details for the Burgos Pipelines and copies of the Presidential Permit applications, as well as information on the Presidential Permit process are available at the following: *http://www.state.gov/e/enr/applicant/applicants/c66757.htm.* Please refer to this Web site or contact the Department at the address listed in the **ADDRESSES** section of this notice.

SUPPLEMENTARY INFORMATION: The Department evaluates Presidential permit applications under E.O. 13337 and E.O. 14432. E.O. 13337 delegates to the Secretary of State the President's authority to receive applications for permits for the construction, connection, operation, or maintenance of facilities for the exportation or importation of petroleum, petroleum products, coal, or other fuels (except for natural gas), at the borders of the United States, and to issue or deny such Presidential Permits upon a national interest determination.

In December 2014, NuStar submitted two applications to the Department. The first application requests a new Presidential Permit to replace a 2006 Presidential Permit, that would: (1) Reflect NuStar's name change from Valero Logistics Operations, L.P. to NuStar Logistics, L.P. as the owner and operator of the Existing Burgos Pipeline, the 34-mile-long 8-inch outer diameter pipeline and border facilities issued a Presidential Permit in 2006 authorizing import and export of light naphtha and (2) allow the Existing Burgos Pipeline and border facilities to transport a broader range of petroleum products than originally authorized, including diesel, gasoline, jet fuel, liquefied petroleum gas, and natural gas liquids. The second application requests that the Department issue a Presidential Permit for construction, connection, operation, and maintenance of a new 10-inch outer diameter pipeline and associated facilities in the same right of way as the Existing Burgos Pipeline to transport the same range of products as the Existing Burgos Pipeline. Both pipelines would connect the Petroleos Mexicanos (PEMEX) Burgos Gas Plant near Reynosa, Tamaulipas, Mexico and the NuStar terminal near Edinburg, Texas in Hidalgo County, Texas at the United States-Mexico border.

Availability of the Draft EA and Preliminary FONSI: Copies of the Draft EA and Preliminary FONSI have been distributed to state and governmental agencies, tribal governments and other interested parties. Printed copies of the document may be obtained by visiting the McAllen Public Library, 4001 N. 23rd St., McAllen, TX 78504, or by contacting the Burgos Project Manager at the above address. They are also available at *http://www.state.gov/e/enr/applicant/applicants/c66757.htm.*

Deborah Klepp,

Director, Office of Environmental Quality and Transboundary Issues, Department of State.

[FR Doc. 2016–10841 Filed 5–6–16; 8:45 am]

BILLING CODE 4710–09–P

TENNESSEE VALLEY AUTHORITY

Meeting of the Regional Energy Resource Council

AGENCY: Tennessee Valley Authority (TVA)

ACTION: Notice of meeting.

SUMMARY: The TVA Regional Energy Resource Council (RERC) will hold a meeting on Tuesday, May 24 and Wednesday, May 25, 2016, regarding regional energy related issues in the Tennessee Valley.

The RERC was established to advise TVA on its energy resource activities and the priorities among competing objectives and values. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2.

The meeting agenda includes the following:

1. Welcome and Introductions
2. TVA Updates
3. Presentations regarding Distributed Energy Resources, including current approaches, new technologies, and the Evolving Market Place
4. Public Comments
5. Council discussion

The RERC will hear views of citizens by providing a public comment session starting at 9:00 a.m. EDT, on Wednesday, May 25. The public comment session may last up to one hour. Persons wishing to speak are requested to register at the door by 8:45 a.m. on Wednesday, May 25, and will be called on during the public comment period. Handout materials should be limited to one printed page. Written comments are also invited and may be mailed to the Regional Energy Resource Council, Tennessee Valley Authority, 400 West Summit Hill Drive, WT–9D, Knoxville TN 37902.

DATES: The meeting will be held on Tuesday, May 24, from 10:00 a.m. to 11:45 a.m. and on Wednesday, May 25, from 8:30 a.m. to noon EDT.

ADDRESSES: The meeting will be held at the Chattanoogan Hotel, 1201 South Broad Street, Chattanooga, Tennessee 37402, and will be open to the public. Anyone needing special access or accommodations should let the contact below know at least a week in advance.

FOR FURTHER INFORMATION CONTACT: Beth Keel, 400 West Summit Hill Drive, WT–9D, Knoxville, Tennessee 37902, (865) 632–6113.

Dated: May 2, 2016.

Joseph J. Hoagland,

Vice President, Enterprise Relations and Innovation, Tennessee Valley Authority.

[FR Doc. 2016–10723 Filed 5–6–16; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2007–28043]

Hours of Service (HOS) of Drivers; American Pyrotechnics Ass'n. (APA) Application for Exemption From the 14-Hour Rule; Extension of Current APA Exemption Period

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for and extension of exemption; request for comments.

SUMMARY: The American Pyrotechnics Association (APA), on behalf of its member companies, has requested additions to and deletions from the list of motor carriers previously granted exemptions for the 2015 and 2016 Independence Day fireworks shows. Fifty-one APA members currently hold such exemptions from the prohibition on driving commercial motor vehicles (CMVs) after the 14th hour after the driver comes on duty. APA requests discontinuance of the exemption for 4 carriers, and new exemptions for 4 carriers, with the total therefore remaining at 51. The "Fixing America's Surface Transportation Act" (FAST Act) extended the expiration date of hours-of-service (HOS) exemptions in effect on the date of enactment of the FAST Act to 5 years from the date of issuance. This notice therefore extends to July 8, 2020, the exemption for the 47 APA members approved in 2015 that wish to retain the exemption. Finally, FMCSA seeks comment on the applications of 4 APA members not previously exempted from the 14-hour rule. Because the FAST Act also authorized new exemptions for a period of up to 5 years, the Agency proposes to grant these 4 motor carriers exemptions that would run through July 8, 2020, and terminate at the same time as the other 47 exemptions. The APA maintains that the terms and conditions of the limited exemption would ensure a level of safety equivalent to, or greater than, the level of safety achieved without the exemption.

DATES: June 8, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2007–28043 using any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: (202) 366–4325. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2007–28043), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, "FMCSA–2007–28043" in the "Keyword" box, and click "Search." When the new screen appears, click on "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, "FMCSA–2007–28043" in the "Keyword" box and click "Search." Next, click "Open Docket Folder" button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption, and explain its terms and conditions. The exemption may be renewed (49 CFR 381.300(b)).

Section 5206(a)(3) of the FAST Act amended 49 U.S.C. 31315 to permit FMCSA to grant exemptions for up to 5 years from the date of issuance, instead of the previous two years [§ 31315(b)(2)]. This statutory provision will be codified in 49 CFR part 381 in a forthcoming rulemaking. Section 5206(b)(2)(A) of the FAST Act also extended all HOS exemptions in effect on the date of enactment to a period of 5 years from the date of issuance.

APA Application for Exemption

The HOS rule in 49 CFR 395.3(a)(2) prohibits the driver of a property-carrying CMV from driving after the 14th hour after coming on duty following 10 consecutive hours off duty. The APA, a trade association representing the domestic fireworks industry, was granted an exemption for 51 member companies for the 2015 and 2016 Independence Day periods [80 FR 37040, June 29, 2015]. APA has requested discontinuing the exemptions for 4 carriers,[1] and adding 4 new carriers, maintaining the total at 51. The 51 exemptions granted to APA members in 2015 (now reduced to 47 exemptions) are extended, pursuant to section 5206(b)(2)(A) of the FAST Act, through the annual Independence Day periods ending on July 8, 2020. The exemptions for the 4 new APA carriers, if granted, would expire on July 8, 2020. Although this is less than the 5-year exemption period authorized by 49 U.S.C. 31315(b)(2), as amended by section 5206(a)(3) of the FAST Act, FMCSA believes that the interests of the APA members and the Agency would best be served by harmonizing, as far as possible, the expiration dates of all such fireworks-related exemptions. It should also be noted that section 5206(b)(2)(A) of the FAST Act extends HOS exemptions in effect on the date of enactment "for a period of 5 years *from the date such exemption was granted*" (emphasis added). FMCSA believes that the intent of the statute was to extend the effective period of an exemption from 2 to 5 years, on the assumption that exemptions begin upon issuance and remain in effect (in most cases) for 2 consecutive years. Since the 2015 fireworks exemption involved 2 separate periods, both ending after "the date such exemption was granted," the Agency believes the FAST Act amendment is best interpreted as extending the end date of the fireworks exemption—namely July 8 of each year—through 2020. Like the other 47 member-companies that operated under the 2015 exemption, the 4 additional member companies would be subject to all of the terms and conditions of the exemption.

The initial APA application for relief from the 14-hour rule was submitted in 2004; a copy is in the docket. That application fully describes the nature of the pyrotechnic operations of the CMV drivers during a typical Independence Day period.

As stated in the 2004 request, the CMV drivers employed by APA member companies are trained pyro-technicians who hold commercial driver's licenses (CDLs) with hazardous materials (HM) endorsements. They transport fireworks and related equipment by CMVs on a very demanding schedule during a brief Independence Day period, often to remote locations. After they arrive, the drivers are responsible for set-up and staging of the fireworks shows.

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[1] Colonial Fireworks, DOT 177274; Fireworks West Internationale, DOT 245423; USA Halloween Planet Inc. dba USA Fireworks, DOT 725457; Western Fireworks Inc., DOT 838585.

The APA states that it is seeking an exemption for an additional 4 member companies because compliance with the current 14-hour rule in 49 CFR 395.3(a)(2) would impose a substantial economic hardship on numerous cities, towns and municipalities, as well as its member companies. To meet the demand for fireworks without the exemption, APA states that its member companies would be required to hire a second driver for most trips. The APA advises that the result would be a substantial increase in the cost of the fireworks shows—beyond the means of many of its members' customers—and that many Americans would be denied this important component of the celebration of Independence Day. The 47 APA member companies currently exempt, as well as the 4 carriers seeking an exemption for the first time, are listed in an appendix to this notice. The 4 new carriers are identified with an asterisk. A copy of the request for the exemption is included in the docket referenced at the beginning of this notice.

Method To Ensure an Equivalent or Greater Level of Safety

The APA believes that the new exemptions would not adversely affect the safety of the fireworks transportation provided by these motor carriers. According to APA, its member-companies have operated under this exemption for 10 previous Independence Day periods without a reported motor carrier safety incident. Moreover, it asserts, without the extra time provided by the exemption, safety would decline because APA drivers would be unable to return to their home base after each show. They would be forced to park the CMVs carrying HM 1.1G, 1.3G and 1.4G products in areas less secure than the motor carrier's home base. As a condition of holding the exemption, each motor carrier would be required to notify FMCSA within 5 business days of any accident (as defined in 49 CFR 390.5) involving the operation of any its CMVs while under this exemption. To date, FMCSA has received no accident notifications, nor is the Agency aware of any accidents reportable under terms of the prior APA exemptions.

In its exemption request, APA asserts that the operational demands of this unique industry minimize the risks of CMV crashes. In the last few days before July 4, these drivers transport fireworks over relatively short routes from distribution points to the site of the fireworks display, and normally do so in the early morning when traffic is light. At the site, they spend considerable time installing, wiring, and safety-checking the fireworks displays, followed by several hours off duty in the late afternoon and early evening prior to the event. During this time, the drivers are able to rest and nap, thereby reducing or eliminating the fatigue accumulated during the day. Before beginning another duty day, these drivers must take 10 consecutive hours off duty, the same as other CMV drivers.

Terms and Conditions of the Exemption

Period of the Exemption

The requested exemption from 49 CFR 395.3(a)(2) would be effective from June 28 through July 8, at 11:59 p.m. local time, each year through 2020.

Terms and Conditions of the Exemption

During the 2016 Independence Day period, the exemption from 49 CFR 395.3(a)(2) would be limited to drivers employed by the 47 motor carriers already covered by the exemption, plus (if approved) the 4 carriers now seeking an exemption. The four carriers that were not included for the 2015 period are identified by an asterisk. Section 395.3(a)(2) prohibits a driver from driving a CMV after the 14th hour after coming on duty and does not permit off-duty periods to extend the 14-hour limit. Drivers covered by this exemption would be able to exclude off-duty and sleeper-berth time of any length from the calculation of the 14-hour limit. This exemption would be contingent on each driver driving no more than 11 hours in the 14-hour period after coming on duty, as extended by any off-duty or sleeper-berth time in accordance with this exception. The exemption would be further contingent on each driver having a full 10 consecutive hours off duty following 14 hours on duty prior to beginning a new driving period. The carriers and drivers must comply with all other requirements of the Federal Motor Carrier Safety Regulations (49 CFR parts 350–399) and Hazardous Materials Regulations (49 CFR parts 105–180).

Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

FMCSA Notification

Exempt motor carriers would be required to notify FMCSA within 5 business days of any accidents (as defined by 49 CFR 390.5) involving the operation of any of their CMVs while under this exemption. The notification must include the following information:

a. Name of the exemption: "APA,"

b. Date of the accident,

c. City or town, and State, in which the accident occurred, or which is closest to the scene of the accident,

d. Driver's name and driver's license number,

e. Vehicle number and State license number,

f. Number of individuals suffering physical injury,

g. Number of fatalities,

h. The police-reported cause of the accident,

i. Whether the driver was cited for violation of any traffic laws, or motor carrier safety regulations, and

j. The total driving time and the total on-duty time of the CMV driver at the time of the accident.

Termination

The FMCSA does not believe the motor carriers and drivers covered by this exemption, if granted, would experience any deterioration of their safety record. However, should this occur, FMCSA would take all steps necessary to protect the public interest, including revocation of the exemption. The FMCSA will immediately revoke the exemption for failure to comply with its terms and conditions. Exempt motor carriers and drivers would be subject to FMCSA monitoring while operating under this exemption.

Issued on: May 2, 2016.

Larry W. Minor,

Associate Administrator for Policy.

Appendix to Notice of APA Application for Exemption From the 14-Hour Rule During 2016–2020 Independence Day Celebrations; Extension of Current Exemption

	Motor carrier	Street address	City, state, zip code	DOT No.
1	American Fireworks Company	7041 Darrow Road	Hudson, OH 44236	103972
2	American Fireworks Display, LLC	P.O. Box 980	Oxford, NY 13830	2115608
3	AM Pyrotechnics, LLC	2429 East 535th Rd	Buffalo, MO 65622	1034961
4	Arthur Rozzi Pyrotechnics	6607 Red Hawk Ct	Maineville, OH 45039	2008107
5	Atlas PyroVision Entertainment Group, Inc.	136 Old Sharon Rd	Jaffrey, NH 03452	789777
6	Central States Fireworks, Inc	18034 Kincaid Street	Athens, IL 62613	1022659
7	East Coast Pyrotechnics, Inc	4652 Catawba River Rd	Catawba, SC 29704	545033
8	Entertainment Fireworks, Inc	13313 Reeder Road SW	Tenino, WA 98589	680942
9	Falcon Fireworks	3411 Courthouse Road	Guyton, GA 31312	1037954
10	Fireworks & Stage FX America	12650 Hwy 67S. Suite B	Lakeside, CA 92040	908304
11	Fireworks by Grucci, Inc	20 Pinehurst Drive	BellPort, NY 11713	324490
12	*Flashing Thunder Fireworks dba Legal Aluminum King Mtg.	700 E Van Buren Street	Mitchell, IA 50461	420413
13	J&J Computing dba Fireworks Extravaganza.	174 Route 17 North	Rochelle Park, NJ 07662	2064141
14	Gateway Fireworks Displays	P.O. Box 39327	St Louis, MO 63139	1325301
15	Great Lakes Fireworks	24805 Marine	East Pointe, MI 48021	1011216
16	Hamburg Fireworks Display, Inc	2240 Horns Mill Road SE	Lancaster, OH	395079
17	Hawaii Explosives & Pyrotechnics, Inc	17–7850 N. Kulani Road	Mountain View, HI 96771	1375918
18	Hollywood Pyrotechnics, Inc	1567 Antler Point	Eagan, MN 55122	1061068
19	Homeland Fireworks, Inc	P.O. Box 7	Jamieson, OR 97909	1377525
20	Island Fireworks Co., Inc	N1597 County Rd VV	Hager City, WI 54014	414583
21	J&M Displays, Inc	18064 170th Ave	Yarmouth, IA 52660	377461
22	Lantis Fireworks, Inc	130 Sodrac Dr., Box 229	N. Sioux City, SD 57049	534052
23	Legion Fireworks Co., Inc	10 Legion Lane	Wappingers Falls, NY 12590	554391
24	Miand Inc. dba Planet Productions (Mad Bomber).	P.O. Box 294, 3999 Hupp Road R31	Kingsbury, IN 46345	777176
25	Martin & Ware Inc. dba Pyro City Maine & Central Maine Pyrotechnics.	P.P. Box 322	Hallowell, ME 04347	734974
26	Melrose Pyrotechnics, Inc	1 Kinsgubury Industrial Park	Kingsbury, IN 46345	434586
27	Precocious Pyrotechnics, Inc	4420–278th Ave NW	Belgrade, MN 56312	435931
28	*Pyro Shows, Inc	115 N 1st Street	LaFollette, TN 37766	456818
29	Pyro Shows of Texas, Inc	6601 9 Mile Azle Rd	Fort Worth, TX 76135	2432196
30	*Pyro Engineering Inc., dba/Bay Fireworks.	400 Broadhollow Rd. Ste #3	Farmindale, NY 11735	530262
31	Pyro Spectaculars, Inc	3196 N Locust Ave	Rialto, CA 92376	029329
32	Pyro Spectaculars North, Inc	5301 Lang Avenue	McClellan, CA 95652	1671438
33	Pyrotechnic Display, Inc	8450 W. St. Francis Rd	Frankfort, IL 60423	1929883
34	Pyrotecnico (S. Vitale Pyrotechnic Industries, Inc.).	302 Wilson Rd	New Castle, PA 16105	526749
35	Pyrotecnico, LLC	60 West Ct	Mandeville, LA 70471	548303
36	Pyrotecnico FX	6965 Speedway Blvd. Suite 115	Las Vegas, NV 89115	1610728
37	Rainbow Fireworks, Inc	76 Plum Ave.	Inman, KS 67546	1139643
38	RES Specialty Pyrotechnics	21595 286th St	Belle Plaine, MN 56011	523981
39	Rozzi's Famous Fireworks, Inc	11605 North Lebanon Rd	Loveland, OH 45140	0483686
40	*Sky Wonder Pyrotechnics, LLC	3626 CR 203	Liverpool, TX 77577	1324580
41	Skyworks, Ltd	13513 W. Carrier Rd	Carrier, OK 73727	1421047
42	Sorgi American Fireworks Michigan, LLC.	935 Wales Ridge Rd	Wales, MI 48027	2475727
43	Spielbauer Fireworks Co, Inc	220 Roselawn Blvd	Green Bay, WI 54301	046479
44	Spirit of 76	6401 West Hwy 40	Columbia, MO 65202	2138948
45	Starfire Corporation	682 Cole Road	Carrolltown, PA 15722	554645
46	Vermont Fireworks Co., Inc./N Northstar Fireworks Co., Inc.	2235 Vermont Route 14 South	East Montpelier, VT 05651	310632
47	Western Display Fireworks, Ltd	10946 S. New Era Rd	Canby, OR 97013	498941
48	Western Enterprises, Inc	P.O. Box 160	Carrier, OK 73727	203517
49	Wolverine Fireworks Display, Inc	205 W Seidlers	Kawkawlin, MI	376857
50	Young Explosives Corp	P.O. Box 18653	Rochester, NY 14618	450304
51	Zambelli Fireworks MFG, Co., Inc	P.O. Box 1463	New Castle, PA 16103	033167

*New applicants for exemption

[FR Doc. 2016–10820 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0371]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials of exemption applications.

SUMMARY: FMCSA announces its decision to deny applications from 7 individuals seeking exemptions from the Federal cardiovascular standard applicable to interstate truck and bus drivers and discusses the reasons for the denials. The Agency reviewed the medical information of each the individuals who applied for an implantable cardioverter defibrillator (ICD) exemption. Based on a review of the applications and following an opportunity for public comment, FMCSA has concluded that the 7 individuals in the notice did not demonstrate they could achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

DATES: Denial letters were sent to each of the individuals listed in this notice on March 1, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief Medical Programs Division, 202–366–4001, U.S. Department of Transportation, FMCSA, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for up to five years if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." FMCSA can renew exemptions for up to an additional five years at the end of each five-year period.[1]

On November 27, 2015, FMCSA published for public notice and comment, FMCSA 2015–0371, listing 7 individuals seeking exemptions for ICDs. Accordingly, the Agency has evaluated each applicant's request to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Evaluation Criteria—Cardiovascular Medical Standard and Advisory Criteria

The individuals included in this notice have requested an exemption from the provisions of 49 CFR 391.41(b)(4), which applies to drivers who operate CMVs in interstate commerce, as defined in 49 CFR 390.5. Section 391.41(b)(4) states that:

> A person is physically qualified to drive a commercial motor vehicle if—
>
> * * * * *
>
> that person has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope [a temporary loss of consciousness due to a sudden decline in blood flow to the brain], dyspnea [shortness of breath], collapse, or congestive cardiac failure.

The FMCSA provides medical advisory criteria as recommendations for use by medical examiners in determining whether drivers with certain medical conditions and drivers who have undergone certain procedures and/or treatments should be certified to operate CMVs in interstate commerce in accordance with the various physical qualification standards in 49 CFR part 391, subpart E. The advisory criteria are currently set out in Appendix A to 49 CFR part 391. The advisory criteria for section 391.41(b)(4) provide, in part, that:

> The term "has no current clinical diagnosis of" is specifically designed to encompass: "a clinical diagnosis of" (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term "known to be accompanied by" is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure.
>
> It is the intent of the Federal Motor Carrier Safety Regulations to render unqualified, a driver who has a current cardiovascular disease which is accompanied by and/or likely to cause symptoms of syncope, dyspnea, collapse, or congestive cardiac failure. However, the subjective decision of whether the nature and severity of an individual's condition will likely cause symptoms of cardiovascular insufficiency is on an individual basis and qualification rests with the medical examiner and the motor carrier.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope (a transient loss of consciousness) or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. See the Evidence Report on "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety," April 2007.[2] A focused research report entitled "Implantable Cardioverter Defibrillators and the Impact of a Shock on a Patient When Deployed," completed for the FMCSA in December 2014, indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety and upholds the findings of the April 2007 report. Copies of the April 2007 report and the December 2014 report are included in the docket for this notice.

Discussion of Public Comments

On November 27, 2015, FMCSA published in a **Federal Register** Notice the names of 7 individuals seeking ICD exemption and requested public comment. The public comment period closed on December 28, 2015. A total of 13 commenters responded to the notice. Each of the comments was favorable towards the applicants continuing to drive CMV's with ICD's. Commenters believed that the individuals seeking exemptions were responsible drivers who had safe professional driving and work histories and believed that their medical conditions did not present safety concerns. One anonymous physician encouraged the FMCSA to accommodate individuals with ICD's that have never deployed or that have not deployed in many years by developing an exception to the general rule that would still protect public safety.

FMCSA's Response

FMCSA acknowledges the commenters' reports of safe driving histories and concerns for the driving careers of the applicants. Based on the available medical literature cited above, however, FMCSA believes that a driver with an ICD is at risk for incapacitation if the device discharges. This risk is combined with the risks associated with the underlying cardiovascular condition for which the ICD has been implanted as a primary or secondary preventive measure.

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[1] 49 U.S.C. 31315(b), as amended by section 5206(a) of the FAST Act, Pub. L. 114–94, div. A, title V, 129 Stat. 1537 (Dec. 4, 2015).

[2] Now available at *http://ntl.bts.gov/lib/30000/30100/30123/Final_CVD_Evidence_Report_v2.pdf.*

Conclusion

FMCSA evaluated the 7 individual exemption requests on their merits, available data from Evidence Reports and Medical Expert Panel opinions on the impact of ICDs on Commercial Motor Vehicle driving, and the public comments received. The Agency has determined that the available medical literature and data does not support a conclusion that granting these exemptions would achieve a level of safety equivalent to or greater than the level of safety maintained without the exemptions. Each applicant has, prior to this notice, received a letter of final disposition on his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

The following 7 applicants are denied exemptions from the cardiovascular standard. Ellis James Benson, Jon Carey, Martin Carter, Carl Jeglum, William Kastner, Mark Todd Smith, Andre Williams.

Issued on: April 28, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10875 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0329]

Qualification of Drivers; Application for Exemptions; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 30 individuals for an exemption from the hearing requirement to operate commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before June 8, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2015–0329 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 30 individuals listed in this notice have recently requested such an exemption from the hearing requirement in 49 CFR 391.41(b)(11), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person

> First perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971).

II. Qualifications of Applicants

James E. Adams

Mr. Adams, age 44, holds an operator's license in Georgia.

Ronald Bagby

Mr. Bagby, age 66, holds an operator's license in Missouri.

Robert Barnett

Mr. Barnett, age 66, holds an operator's license in Michigan.

Jason A. Beutal

Mr. Beutal, age 39, holds an operator's license in Wisconsin.

Benjamin Bottoms

Mr. Bottoms, age 37, holds an operator's license in Virginia.

Edward Broeker

Mr. Broeker, age 54, holds an operator's license in California.

John Brown

Mr. Brown, age 59, holds a class A CDL in Minnesota.

Chris C. Calogar

Mr. Calogar, age 46, holds an operator's license in Ohio.

Richard P. Carney

Mr. Carney, age 58, holds an operator's license in New York.

David Cochran

Mr. Cochran, age 32, holds an operator's license in Washington.

Mark Deaken

Mr. Deaken, age 27, holds a class A CDL in Montana.

Ronald Doiron

Mr. Doiron, age 49, holds an operator's license in Massachusetts.

Glenn Ferguson

Mr. Ferguson, age 52, holds an operator's license in Texas.

James Griffin

Mr. Griffin, age 59, holds an operator's license in Tennessee.

James Harris

Mr. Harris, age 55, holds an operator's license in Florida.

Kristina Hundorf

Ms. Hundorf, age 50, holds an operator's license in California.

Kenneth Jones

Mr. Jones, age 55, holds a class A CDL in New Jersey.

Paul Mansfield

Mr. Mansfield, age 39, holds an operator's license in Kansas.

Eric Muniz

Mr. Muniz, age 38, holds an operator's license in Oklahoma.

Anthony Panto

Mr. Panto, age 57, holds a class A CDL in New Jersey.

David Pogue

Mr. Pogue, age 31, holds a class B CDL in Missouri.

Jeffrey Prag

Mr. Prag, age 56, holds a class AM CDL in Georgia.

James Prine

Mr. Prine, age 67, holds an operator's license in Arkansas.

Steven Tipton

Mr. Tipton, age 50, holds an operator's license in Iowa.

Eric Trevino

Mr. Trevino, age 30, holds an operator's license in Texas.

Wayne Turner

Mr. Turner, age 26, holds an operator's license in Illinois.

Paul Wentworth

Mr. Wentworth, age 48, holds an operator's license in Texas.

Kevin L.Wickman

Mr. Wickman, age 51, holds an operator's license in Iowa.

Robert G. Wilson

Mr. Wilson, age 64, holds an operator's license in Tennessee.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0329 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final determination any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0329 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to this notice.

Issued on: April 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10789 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0039]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 65 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before June 8, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2016–0039 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 65 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b) (3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

II. Qualifications of Applicants

Israel R.H. Alvarez

Mr. Alvarez, 32, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Alvarez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Alvarez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Kansas.

Matthew P. Ambrose

Mr. Ambrose, 39, has had ITDM since 2012. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ambrose understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ambrose meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Christopher M. Anderson

Mr. Anderson, 41, has had ITDM since 1996. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Anderson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Anderson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Arkansas.

Juan Arvizu

Mr. Arvizu, 45, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Arvizu understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Arvizu meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Florida.

Steven E. Beining

Mr. Beining, 53, has had ITDM since 1996. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Beining understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Beining meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Steven Belback

Mr. Belback, 57, has had ITDM since 1999. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Belback understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Belback meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Joseph N. Beller

Mr. Beller, 64, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Beller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Beller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

Roger D. Bragg

Mr. Bragg, 47, has had ITDM since 2016. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bragg understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bragg meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from West Virginia.

Jonathan Bu

Mr. Bu, 27, has had ITDM since 1999. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bu understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bu meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from New Jersey.

John Ciesmelewski

Mr. Ciesmelewski, 61, has had ITDM since 2012. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ciesmelewski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ciesmelewski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from New Jersey.

Ernest W. Collett

Mr. Collett, 59, has had ITDM since 2006. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Collett understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Collett meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

Daniel C. Crider

Mr. Crider, 38, has had ITDM since 1991. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Crider understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Crider meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Minnesota.

Charla J. Donahy

Ms. Donahy, 38, has had ITDM since 2015. Her endocrinologist examined her in 2015 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Donahy understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Donahy meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2015 and certified that she does not have diabetic retinopathy. She holds an operator's license from Texas.

Jason A. Edington

Mr. Edington, 44, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Edington understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Edington meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Tennessee.

Richard D. Florio, Jr.

Mr. Florio, 44, has had ITDM since 1989. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Florio understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Florio meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New York.

Tyler J. Francis

Mr. Francis, 66, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Francis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Francis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Calvin L. Frew

Mr. Frew, 56, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Frew understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Frew meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Idaho.

Juda Friedman

Mr. Friedman, 35, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Friedman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Friedman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from New York.

Dean Gage

Mr. Gage, 50, has had ITDM since 1986. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gage understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gage meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from New York.

William Gallagher

Mr. Gallagher, 62, has had ITDM since 1990. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gallagher understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gallagher meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Michael A. Gervasio

Mr. Gervasio, 58, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gervasio understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gervasio meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New York.

Harvey E. Gordon

Mr. Gordon, 65, has had ITDM since 2010. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gordon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gordon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

James W. Gorman, Jr.

Mr. Gorman, 58, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gorman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gorman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Maryland.

Christopher L. Greene

Mr. Greene, 37, has had ITDM since 2004. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Greene understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Greene meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Wyoming.

Gregor C. Guisewhite

Mr. Guisewhite, 53, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Guisewhite understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Guisewhite meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Aleaha M. Hallgren

Ms. Hallgren, 24, has had ITDM since 2016. Her endocrinologist examined her in 2016 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Hallgren understands diabetes management and monitoring, has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Hallgren meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2016 and certified that she does not have diabetic retinopathy. She holds a Class B CDL from Illinois.

Dennis T. Harding

Mr. Harding, 56, has had ITDM since 2004. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Harding understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Harding meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Minnesota.

Brandon R. Hart

Mr. Hart, 34, has had ITDM since 2006. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hart understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hart meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Texas.

Carl E. Hawkins

Mr. Hawkins, 69, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hawkins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hawkins meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Craig J. Hebbeln

Mr. Hebbeln, 51, has had ITDM since 1986. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hebbeln understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hebbeln meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Iowa.

Stephen E. Hochmiller

Mr. Hochmiller, 60, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hochmiller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hochmiller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Colorado.

Jack V. Holloway

Mr. Holloway, 53, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Holloway understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Holloway meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Illinois.

Richard L. Hubbard

Mr. Hubbard, 65, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hubbard understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hubbard meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Sondra R. Jones

Ms. Jones, 62, has had ITDM since 2015. Her endocrinologist examined her in 2016 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Jones understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Jones meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2016 and certified that she does not have diabetic retinopathy. She holds a Class A CDL from Texas.

John F. Kelleher, Jr.

Mr. Kelleher, 75, has had ITDM since 2010. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kelleher understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kelleher meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

Stephen A. Kinney

Mr. Kinney, 49, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kinney understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kinney meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Michigan.

Russell L. Koehn

Mr. Koehn, 65, has had ITDM since 2011. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Koehn understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Koehn meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Timothy C. LaRue

Mr. LaRue, 63, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. LaRue understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. LaRue meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable proliferative diabetic retinopathy. He holds a Class A CDL from Florida.

Joseph M. Lopes

Mr. Lopes, 61, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lopes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lopes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Hampshire.

Ronald G. Mundt

Mr. Mundt, 60, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mundt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mundt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Wisconsin.

Derrick C. Nailon

Mr. Nailon, 35, has had ITDM since 2010. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Nailon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Nailon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

William B. Onimus

Mr. Onimus, 46, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Onimus understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Onimus meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Jesus O. Orellana

Mr. Orellana, 55, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Orellana understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Orellana meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Rhode Island.

Victor M. Orta

Mr. Orta, 55, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Orta understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Orta meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

Travis J. Partridge

Mr. Partridge, 27, has had ITDM since 1998. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Partridge understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Partridge meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Iowa.

Adam L. Pennings

Mr. Pennings, 25, has had ITDM since 2001. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pennings understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pennings meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Minnesota.

Tyler D. Pittsley

Mr. Pittsley, 24, has had ITDM since 2004. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pittsley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pittsley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from North Dakota.

William D. Powell

Mr. Powell, 46, has had ITDM since 1981. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Powell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Powell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Illinois.

Lee A. Pulda

Mr. Pulda, 58, has had ITDM since 1998. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pulda understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pulda meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Dustin L. Renfroe

Mr. Renfroe, 27, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Renfroe understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Renfroe meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Texas.

Robert D. Risk

Mr. Risk, 41, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Risk understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Risk meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Indiana.

David C. Roberts

Mr. Roberts, 40, has had ITDM since 1988. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Roberts understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Roberts meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from South Dakota.

Richard L. Robinson

Mr. Robinson, 62, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Robinson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Robinson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Michigan.

Randy Rowe

Mr. Rowe, 34, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rowe understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rowe meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Illinois.

William K. Sawyer II

Mr. Sawyer, 37, has had ITDM since 2002. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sawyer understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sawyer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from New Mexico.

Jeffrey J. Schnacker

Mr. Schnacker, 44, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Schnacker understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schnacker meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Nebraska.

Jeffrey D. Smith

Mr. Smith, 47, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Smith understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Smith meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Maryland.

Anthony G. Stellatos

Mr. Stellatos, 52, has had ITDM since 2010. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stellatos understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stellatos meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Trent A. Stuber

Mr. Stuber, 31, has had ITDM since 2006. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stuber understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stuber meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Samer M. Valle

Mr. Valle, 51, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Valle understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Valle meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

LaDon L. Wallin

Mr. Wallin, 46, has had ITDM since 1990. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wallin understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wallin meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Minnesota.

Thomas J. Warren

Mr. Warren, 60, has had ITDM since 2016. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Warren understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Warren meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Richard D. Webb

Mr. Webb, 60, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Webb understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Webb meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New York.

Grady L. Wilson, Jr.

Mr. Wilson, 61, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wilson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wilson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Florida.

Karl S. Yauneridge

Mr. Yauneridge, 24, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Yauneridge understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Yauneridge meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Maryland.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441)[1]. The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice.

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[1] Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136 (e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2016–0039 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2016–0039 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to this notice.

Issued on: May 2, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10873 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2015–0119]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt nine individuals from the regulatory requirement that interstate commercial motor vehicle (CMV) drivers have "no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV." The exemptions enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions were effective on December 16, 2015. The exemptions expire on December 16, 2017.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov*, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On November 12, 2015, FMCSA published a notice announcing receipt of applications from 13 individuals requesting an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a CMV in interstate commerce and requested comments from the public (80 FR 70065). The public comment period closed on December 14, 2015, and seven comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to nine individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person

> Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. The advisory criteria found in Appendix A to 49 CFR 391.41, states that:

> If an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause that did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.
>
> In those individual cases where a driver had a seizure or an episode of loss of

> consciousness that resulted from a known medical condition (*e.g.,* drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has recovered fully from that condition, has no existing residual complications, and is not taking anti-seizure medication.
>
> Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5-year period or more.

As a result of medical examiners misinterpreting advisory criteria as regulation, numerous drivers have been prohibited from operating a CMV in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner based on the physical qualification standards and medical best practices.

In reaching the decision to grant these exemption requests, the Agency considered the 2007 recommendations of the Agency's Medical Expert Panel (MEP). The January 15, 2013 (78 FR 3069) **Federal Register** notice provides the current MEP recommendations which is the criteria the Agency uses to grant seizure exemptions.

These nine applicants have been seizure-free over a range of 5 to 44 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last two years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially. A summary of each applicant's seizure history was discussed in the November 12, 2015 **Federal Register** notice and will not be repeated in this notice.

III. Discussion of Comments

Seven commenters responded to this notice, six of whom specifically expressed support for applicant Thomas Vivirito and one in support of her husband receiving an exemption. The Agency has determined that nine applicants should be granted an exemption.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

The Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System (CDLIS) for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System (MCMIS). For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency (SDLA). The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and includes the following: (1) Each individual must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each individual must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each individual must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each individual must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Conclusion

Based upon its evaluation of the nine exemption applications, FMCSA exempts the following drivers from the epilepsy/seizure standard in 49 CFR 391.41(b)(8), subject to the requirements cited above: Kenneth Lee Brown (WY), Douglas Ray Burkhardt (SD); Curtis Alan Hartman (MD); Wendell Frank Headley, Jr. (MO); Gregory L. Hrutkay (PA); Michael William Ketchum, Sr. (MI); Marion Franklin Legg, Jr. (MD); Alvin Clarence Strite (PA); and Thomas B. Vivirito (PA).

In accordance with 49 U.S.C. 31315(b)(1), each exemption is valid for 2 years, unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The individual fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315. If the exemption is still effective at the end of the 2-year period, the individual may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: April 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10796 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0322]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 27 individuals for an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions would enable these

individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs for up to 2 years in interstate commerce.

DATES: Comments must be received on or before June 8, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2015–0322 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov* as described in the system records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, or via email at *fmcsamedical@dot.gov,* or by letter to FMCSA, Room W64–113, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for up to a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statutes allow the Agency to renew exemptions at the end of the 2-year period. The 27 individuals listed in this notice have requested an exemption from the epilepsy prohibition in 49 CFR 391.41(b)(8), which applies to drivers who operate CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person

> Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. The advisory criteria found in Appendix A to 49 CFR 391.41, states that

> If an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause that did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.
>
> In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (*e.g.,* drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has recovered fully from that condition, has no existing residual complications, and is not taking anti-seizure medication.
>
> Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5-year period or more.

As a result of medical examiners misinterpreting advisory criteria as regulation, numerous drivers have been prohibited from operating a CMV in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner based on the physical qualification standards and medical best practices.

II. Qualifications of Applicants

Hamilton Barnard

Mr. Barnard is a 38 year-old driver in California. He has a history of a seizure disorder and has remained seizure free since 2005. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Barnard receiving an exemption.

William E. Beaver

Mr. Beaver is a 50 year-old class A CDL holder in Minnesota. He has a history of a single seizure in January 2015, likely secondary to cyclosporine use and posterior reversible encephalopathy syndrome. He discontinued taking anti-seizure in May 2015. His physician states that he is supportive of Mr. Beaver receiving an exemption.

Paul V. Carlson

Mr. Carlson is a 38 year-old driver in Minnesota. He has a history of a single seizure following brain surgery for treatment of an obstructive hydrocephalus ventricular colloid cyst in 2015. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Carlson receiving an exemption.

Edward J. Carder Jr.

Mr. Carder is a 37 year-old driver in Ohio. He has a history of a single seizure in 2010. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Carder receiving an exemption.

Timothy M. Crampton

Mr. Crampton is a 24 year-old driver in Connecticut. He has a history of epilepsy and has remained seizure free since 2002. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Crampton receiving an exemption.

Henry Dennis Counts Jr.

Mr. Counts is a 39 year-old driver in Maryland. He has a history of a seizure disorder and has remained seizure free since 2003. He takes anti-seizure medication with the dosage and frequency remaining the same since 2006. His physician states that he is supportive of Mr. Counts receiving an exemption.

Tommy Joe Cox

Mr. Cox is a 53 year-old class B CDL holder in Kentucky. He has a history of epilepsy and has remained seizure free since 2014. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Cox receiving an exemption.

Michael D. Davis

Mr. Davis is a 47 year-old class A CDL holder in Maine. He has a history of a seizure disorder and has remained seizure free since 1998. He takes anti-seizure medication with the dosage and frequency remaining the same since 2002. His physician states that he is supportive of Mr. Davis receiving an exemption.

William Garvin

Mr. Garvin is a 38 year-old driver in New Hampshire. He has a history of a seizure in 2015. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that she is supportive of Mr. Garvin receiving an exemption.

Charlie E. Getchell

Mr. Getchell is a 57 year-old class B CDL holder in Wisconsin. He has a history of a single seizure and has remained seizure free since 1986. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Getchell receiving an exemption.

Dennis R. Giles

Mr. Giles is a 56 year-old class B CDL holder in Indiana. He has a history of a single seizure in 2010 and has remained seizure free since that time. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Giles receiving an exemption.

Jeremiah Gonzales

Mr. Gonzales is a 34 year-old class A CDL holder in Colorado. He has a history of a seizure disorder and has remained seizure free since 2009. He takes anti-seizure medication with the dosage and frequency remaining the same since 2013. His physician states that he is supportive of Mr. Gonzales receiving an exemption.

Robert W. Goddard

Mr. Goddard is a 53 year-old class B CDL holder in New Hampshire. He has a history of a seizure disorder and has remained seizure free since 2006. He takes anti-seizure medication with the dosage and frequency remaining the same since 2013. His physician states that he is supportive of Mr. Goddard receiving an exemption.

Roderick L. Haslip

Mr. Haslip is a 54 year-old class A CDL holder in New York. He has a history of a seizure disorder and has remained seizure free since 2010. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Haslip receiving an exemption.

Larry G. Hediger

Mr. Hediger is a 59 year-old class A CDL holder in Illinois. He has a history of epilepsy and has remained seizure free since 2004. He takes anti-seizure medication with the dosage and frequency remaining the same since 2006. His physician states that he is supportive of Mr. Hediger receiving an exemption.

Martin Lancaster

Mr. Lancaster is a 51 year-old driver in Maine. He has a history of a seizure disorder and has remained seizure free since 2001. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Lancaster receiving an exemption.

Philip A. Logan

Mr. Logan is a 35 year-old driver in South Carolina. He has a history of a seizure disorder and has remained seizure free since 1998. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Logan receiving an exemption.

Eric J. McVetty

Mr. McVetty is a 29 year-old class B CDL holder in New Hampshire. He has a history of a seizure disorder and has remained seizure free since 2005. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. McVetty receiving an exemption.

Doug William Outfleet

Mr. Outfleet is a 55 year-old driver in California. He has a history of a seizure disorder and has remained seizure free since 2010. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Outfleet receiving an exemption.

David J. Parris

Mr. Parris is a 22 year-old driver in Illinois. He has a history of a seizure disorder and has remained seizure free since 2012. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Parris receiving an exemption.

Donald John Richmond

Mr. Richmond is a 63 year-old driver in South Carolina. He has a history of a seizure disorder and has remained seizure free since 1980. He takes anti-seizure medication with the dosage and frequency remaining the same since 2001. His physician states that he is supportive of Mr. Richmond receiving an exemption.

Shawn E. Sands

Mr. Sands is a 32 year-old driver in Illinois. He has a history of epilepsy and has remained seizure free since 2009. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Sands receiving an exemption.

Robert B.Skinner

Mr. Skinner is a 43 year-old driver in Ohio. He has a history of a brain tumor and has remained seizure free since 2007. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Skinner receiving an exemption.

Shaen Smith

Mr. Smith is a 47 year-old driver in Minnesota. He has a history of epilepsy and has remained seizure free since 1998. He takes anti-seizure medication with the dosage and frequency remaining the same since 2013. His physician states that he is supportive of Mr. Smith receiving an exemption.

Kevin Lee Sprinkle

Mr. Sprinkle is a 35 year-old class A CDL holder in North Carolina. He has a history of juvenile epilepsy and has remained seizure free since 2005. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Sprinkle receiving an exemption.

Patrick Trimbo

Mr. Trimbo is a 53 year-old class A CDL holder in Minnesota. He has a history of a seizure disorder and has remained seizure free since 1996. He takes anti-seizure medication with the dosage and frequency remaining the same since 2008. His physician states that he is supportive of Mr. Trimbo receiving an exemption.

Alan Washabaugh

Mr. Washabaugh is a 57 year-old class A CDL holder in Pennsylvania. He has a history of a seizure disorder and has remained seizure free since 1996. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. His physician states that he is supportive of Mr. Washabaugh receiving an exemption.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number "FMCSA–2015–0322" and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and materials received during the comment period. FMCSA may issue a final determination any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0322 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to this notice.

Issued on: April 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10795 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2015–0320]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt eight individuals from the regulatory requirement that interstate commercial motor vehicle (CMV) drivers have "no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV." The exemptions enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions were effective on January 21, 2016. The exemptions expire on January 21, 2018.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On December 21, 2015, FMCSA published a notice announcing receipt of applications from 17 individuals requesting an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a CMV in interstate commerce and requested comments from the public (80 FR 70065). The public comment period closed on January 20, 2016, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to eight individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person

> Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. The advisory criteria found in Appendix A to 49 CFR 391.41, states that:

> If an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause that did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.
>
> In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (*e.g.*, drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has recovered fully from that condition, has no existing residual complications, and is not taking anti-seizure medication.
>
> Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5-year period or more.

As a result of medical examiners misinterpreting advisory criteria as regulation, numerous drivers have been prohibited from operating a CMV in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner based on the physical qualification standards and medical best practices.

In reaching the decision to grant these exemption requests, the Agency considered the 2007 recommendations of the Agency's Medical Expert Panel (MEP). The January 15, 2013 (78 FR 3069) **Federal Register** notice provides the current MEP recommendations which is the criteria the Agency uses to grant seizure exemptions.

These eight applicants have been seizure-free over a range of 13 to 43 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last two years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially. A summary of each applicant's seizure history was discussed in the December 21, 2015 **Federal Register** notice and will not be repeated in this notice.

III. Discussion of Comments

There were no comments in response to this notice. The Agency has determined that eight applicants should be granted an exemption.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

The Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System (CDLIS) for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System (MCMIS). For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency (SDLA). The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and includes the following: (1) Each individual must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each individual must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each individual must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each individual must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Conclusion

Based upon its evaluation of the eight exemption applications, FMCSA exempts the following drivers from the epilepsy/seizure standard in 49 CFR 391.41(b)(8), subject to the requirements cited above: James E. Allen (ME); Thomas A DeAngelo (IL); Nathan Dermer (AK); Daniel Lloyd Halstead (NV); Kevin Mathis (NJ); Toriano T. Mitchell (OH); Thomas A. Mitman (NY) and Tyler W. Schaefor (ME).

In accordance with 49 U.S.C. 31315(b)(1), each exemption is valid for 2 years, unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The individual fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315. If the exemption is still effective at the end of the 2-year period, the individual may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: April 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10794 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0348]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 20 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions were granted March 10, 2016. The exemptions expire on March 10, 2018.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On February 8, 2016, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (81 FR 6573). That notice listed 20 applicants' case histories. The 20 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 20 applications on their merits and made a determination to grant exemptions to each of them.

III. Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

> A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 20 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, complete loss of vision, corneal dystrophy, corneal transplant, macular degeneration, macular hole, optic nerve hypoplasia, prosthetic eye, refractive amblyopia, and retinal detachment. In most cases, their eye conditions were not recently developed. Twelve of the applicants were either born with their vision impairments or have had them since childhood.

The 8 individuals that sustained their vision conditions as adults have had it for a range of 4 to 40 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 20 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision in careers ranging for 3 to 35 years. In the past three years, 3 drivers were involved in crashes, and 1 driver was convicted of a moving violation in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the February 8, 2016 notice (81 FR 6573).

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., "Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process," Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 20 applicants, 3 drivers were involved in crashes, and 1 driver was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 20 applicants listed in the notice of February 8, 2016 (81 FR 6573).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 20 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following:

(1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

V. Discussion of Comments

FMCSA received no comments in this proceeding.

VI. Conclusion

Based upon its evaluation of the 20 exemption applications, FMCSA exempts the following drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)):

Lonnie D. Barber (NC)
Thomas M. Bowman (OH)
Daniel T. Brown (OH)
Samuel S. Byler (PA)
Robert Fawcett, Jr. (PA)
James T. Friesner, Jr. (OH)
Harry J. Glynn (LA)
Jerry L. Gray (AL)
Lloyd Hinton (NY)
James M. Knef (NJ)
Cody McDonnell (OR)
Brandon J. Michalko (NY)
John L. Ratayczak (WI)
Dennis C. Rokes (IA)
Brian W. Roughton (MO)
Eric A. Simonsen (SC)
Brian S. Tuttle (KY)
Steven A. Van Raalte (IL)
Marvin L. Wernimont (IA)
Brian J. Yole (TX)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: May 2, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10891 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1999–6480; FMCSA–2000–7363; FMCSA–2004–17195; FMCSA–2005–23099; FMCSA–2007–0071; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2010–0050; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0040; FMCSA–2012–0104; FMCSA–2013–0174; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0005]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 43 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: Each group of renewed exemptions are effective from the dates stated in the discussions below. Comments must be received on or before June 8, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Numbers: Docket No. [Docket No. FMCSA–1999–6480; FMCSA–2000–7363; FMCSA–2004–17195; FMCSA–2005–23099; FMCSA–2007–0071; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2010–0050; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0040; FMCSA–2012–0104; FMCSA–2012–0340; FMCSA–2013–0174; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0005], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov*, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 43 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 43 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. Each individual is identified according to the renewal date.

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. The following group(s) of drivers will receive renewed exemptions effective in the month of June and are discussed below.

As of June 3, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 34 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (64 FR 68195; 65 FR 20251; 65 FR 45817; 65 FR 77066; 67 FR 17102; 67 FR 38311; 68 FR 1654; 69 FR 17263; 69 FR 17267; 69 FR 26921; 69 FR 31447; 70 FR 7545; 71 FR 4194; 71 FR 13450; 71 FR 16410; 71 FR 27033; 73 FR 6242; 73 FR 9158; 73 FR 11989; 73 FR 16950; 73 FR 28186; 74 FR 60022; 74 FR 65842; 75 FR 4623; 75 FR 9477; 75 FR 9480; 75 FR 9482; 75 FR 9484; 75 FR 14656; 75 FR 22176; 75 FR 27623; 75 FR 28682; 77 FR 10604; 77 FR 10606; 77 FR 13689; 77 FR 15184; 77 FR 17107; 77 FR 17108; 77 FR 17109; 77 FR 27845; 77 FR 27849; 77 FR 27850; 77 FR 29447; 79 FR 1908; 79 FR 10606; 79 FR 10619; 79 FR 14328; 79 FR 14331; 79 FR 14333; 79 FR 14571; 79 FR 17642; 79 FR 18391; 79 FR 18392; 79 FR 21996; 79 FR 22003; 79 FR 27043; 79 FR 28588; 79 FR 29498):

Thomas R. Abbott (TN)
Dean R. Allen (OR)
Robert J. Ambrose (MA)
Rodney R. Anderson (PA)
Ernie E. Black (NC)
Gary O. Brady (WV)
Marland L. Brassfield (TX)
Larry D. Buchanan (NM)
Michael B. Canedy (MN)
Melvin D. Clark (GA)
Dean E. Dexter (SD)
Scott E. Elliot (NH)
Rojelio Garcia-Pena (MI)
Grant G. Gibson (MN)
Stephen H. Goldcamp (OH)
Wai F. King (IL)
Eric W. Kopmann (MO)
Dennis E. Krone (IL)
George E. Lewis (OH)
Travis J. Luce (MI)
Phillip D. Mathys (OH)
Thomas J. Mavraganis (IL)
Richard J. McKenzie, Jr. (MD)
Christopher J. Meerten (OR)
Jason T. Montoya (NM)
Michael Pace (TX)
Tommy L. Ray, Jr. (AL)
George S. Rayson (OH)
Joe A. Root (MN)
Carl D. Short (MO)
Lewis H. West, Jr. (MA)
Donald G. Wilcox (OR)
David E. Williford (NC)
Jimmy S. Zamora, Jr. (TX)

The drivers were included in one of the following dockets: Docket Nos. FMCSA–1999–6480; FMCSA–2000–7363; FMCSA–2004–17195; FMCSA–2005–23099; FMCSA–2007–0071; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2010–0050; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2013–0174; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0004. Their exemptions are effective as of June 3, 2016 and will expire on June 3, 2018.

As of June 6, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 3 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (77 FR 23799; 77 FR 33558; 79 FR 27365):

Rudolph Bisschop (MA)
Richard Doroba (IL)
Tommy Thomas (CA)

The drivers were included in one of the following dockets: Docket No. FMCSA–2012–0040. Their exemptions are effective as of June 6, 2016 and will expire on June 6, 2018.

As of June 17, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual, DelRay V. Ryckman (SD), has satisfied the conditions for obtaining a renewed exemption from the vision requirements (79 FR 27681; 79 FR 38649).

The driver was included in the following docket: Docket No. FMCSA–2014–0005. The exemption is effective as of June 17, 2016 and will expire on June 17, 2018.

As of June 27, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 5 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (77 FR 27847; 77 FR 38386; 79 FR 29495):

Matthew G. Epps (FL)
Michael E. McAfee (KY)
Joe Ramirez (CA)
James E. Sikkink (IL)
John C. Smith (IL)

The drivers were included on the following docket: Docket No. FMCSA–2012–0104. Their exemptions are effective as of June 27, 2016 and will expire on June 27, 2018.

Each of the 42 applicants listed in the groups above has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by June 8, 2016.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 42 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket numbers

FMCSA–1999–6480; FMCSA–2000–7363; FMCSA–2004–17195; FMCSA–2005–23099; FMCSA–2007–0071; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2010–0050; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0040; FMCSA–2012–0104; FMCSA–2013–0174; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0005 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–1999–6480; FMCSA–2000–7363; FMCSA–2004–17195; FMCSA–2005–23099; FMCSA–2007–0071; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2010–0050; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0040; FMCSA–2012–0104; FMCSA–2013–0174; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0005 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to this notice.

Issued on: April 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–10797 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2016–0002–N–13]

Agency Request for Regular Processing of Collection of Information by the Office of Management and Budget

AGENCY: Federal Railroad Administration (FRA), United States Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: Consistent with the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this document provides notice that FRA is submitting the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) to collect information on railroads' implementation of positive train control (PTC) systems on a quarterly form. FRA requests regular processing and OMB authorization to collect the information on the quarterly form identified below 30 days after publication of this notice for a period of three years.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with any public applicable supporting documentation, may be obtained by calling FRA's Office of Safety Information Collection Clearance Officer, Robert Brogan at (202) 493–6292, or FRA's Office of Administration Information Collection Clearance Officer, Kimberly Toone at (202) 493–6132; these numbers are not toll-free; or by contacting Mr. Brogan via facsimile at (202) 493–6216 or Ms. Toone via facsimile at (202) 493–6497, or via email by contacting Mr. Brogan at *Robert.Brogan@dot.gov,* or by contacting Ms. Toone at *Kim.Toone@dot.gov.* Comments or questions about any aspect of this ICR should be directed to OMB's Office of Information and Regulatory Affairs, Attn: FRA OMB Desk Officer.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 20157, as amended by the Positive Train Control Enforcement and Implementation Act of 2015 (PTCEI Act), FRA must conduct compliance reviews, at least annually, to ensure each railroad is complying with its revised PTC implementation plan (PTCIP). The PTCEI Act requires railroads to provide information to FRA that FRA determines is necessary to adequately conduct such compliance reviews. *See* 49 U.S.C. 20157(c)(2).

To effectively monitor industry's implementation of PTC systems, FRA is proposing to require each subject railroad to submit quarterly reports on its implementation progress, in addition to the annual progress reports the PTCEI Act mandated, under FRA's statutory and regulatory investigative authorities. *See* 49 U.S.C. 20157(c)(2); *see also* 49 U.S.C. 20107, 20902; 49 CFR 236.1009(h). Specifically, FRA is proposing that, in addition to the annual report due each March 31 under 49 U.S.C. 20157(c)(1), railroads must provide quarterly progress reports covering the preceding three-month period and submit the forms to FRA on the dates in the following table until full PTC system implementation is completed:

	Coverage period	Due dates for quarterly reports
Q1	January 1–March 31	June 30, 2016, and each April 30 thereafter.
Q2	April 1–June 30	July 31.
Q3	July 1–September 30	October 31.
Q4	October 1—December 31	January 31.

FRA delayed the due date for submitting the first quarterly report to allow time for the normal 60 days of notice and public comment to FRA, and the additional 30 days of public comment to OMB while the submission undergoes OMB review as required under the PRA and its concomitant regulations. *See* 44 U.S.C. 3501–3520; 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a).

FRA is proposing that each railroad must submit its quarterly progress reports on Form FRA F 6180.165 using FRA's Secure Information Repository (SIR) at *https://sir.fra.dot.gov.* FRA is proposing to let the less detailed monthly reporting that it currently requires (approved under OMB No. 2130–0553) expire in June 2016 when railroads would be required to begin providing the quarterly progress reports.

II. Public Participation

On March 7, 2016, FRA published a notice in the **Federal Register** seeking public comment on the proposed Quarterly PTC Progress Report Form. 81 FR 11878, Mar. 7, 2016. By letter dated April 12, 2016, the Association of American Railroads (AAR) submitted comments on behalf of itself and its member railroads. By letter and email responses dated April 12, 2016, the American Public Transportation Association (APTA) provided comments from Metra, the Utah Transit Authority, the Tri-County Metropolitan Transportation District of Oregon, and the Fort Worth Transportation Authority.

On April 19, 2016, FRA held a meeting on the proposed Quarterly PTC Progress Report Form to offer the affected regulated entities a forum to provide additional comments and feedback to FRA. Representatives from, and members of, AAR, APTA, and the American Short Line and Regional Railroad Association (ASLRRA) attended the meeting. FRA will publish minutes from the meeting in the docket as soon as practicable.

FRA received the following summarized comments on the version of the Quarterly PTC Progress Report that FRA proposed on March 7, 2016. 81 FR 11878. FRA has modified the proposed form based on the industry's comments and requests for clarification in those comments and in the meeting discussed above. The revised form that FRA will submit to OMB for review and approval is attached to this notice.

A. Comments on Section 1—Summary

AAR commented that the column heading "Quantity Completed As of Applicable Quarter" in the summary section was unclear and asked FRA to clarify whether that column refers to the quantity completed for the year as of the end of the quarter or just the quantity completed during the particular quarter. In response, FRA modified the heading to read "Cumulative Quantity Completed to Date" to clarify that FRA wants each railroad to provide a running cumulative total in the high-level summary table.

At the public meeting, CSX Transportation, Inc. (CSX) asked whether the row "Locomotives Fully Equipped" refers to locomotives with all necessary hardware installed or to locomotives with all necessary hardware installed that are mission capable and could begin operating in PTC service. FRA added the words "and PTC operable" to clarify its intent.

Additionally, FRA eliminated the rows "Back Office Locations Completely Installed and Fully Operable" and "Dispatching Locations Completely Installed and Fully Operable" from the summary section, as AAR requested.

Because several commenters requested FRA to make the Quarterly PTC Progress Report consistent with the Annual PTC Progress Report FRA published (see *https://www.fra.dot.gov/eLib/details/L17366*) as much as possible (where the questions overlap), FRA also added a comment box to the summary section and quantitative rows entitled "Route Miles in Testing or Revenue Service Demonstration" and "Route Miles in PTC Operation."

B. Comments on Section 2—Quarterly Update on Spectrum

Based on AAR's and ASLRRA's comments at the public meeting that spectrum is difficult to quantify in the manner requested in the proposed form, FRA modified the quarterly form so a railroad can simply identify a spectrum coverage area and select from a dropdown menu the applicable status: Not acquired/not available for use; acquired but not available for use; or acquired and available for use.

AAR asked FRA to clarify whether the section on spectrum is asking for a report about only the spectrum coverage missing and left to acquire or about all spectrum coverage. FRA clarified at the public meeting and in the soon-to-be-posted meeting minutes that a railroad should base its progress report on the information it provided in its revised PTCIP. The PTCEI Act required each railroad to identify in its revised PTCIP the calendar year(s) when spectrum will be acquired and will be available for use in each area as needed for PTC implementation, if such spectrum was *not* already acquired and available for use. 49 U.S.C. 20157(a)(2)(A)(iii)(I). To make the form clearer, FRA added a footnote to the spectrum table, explaining that if the railroad reported in its revised PTCIP it had acquired all necessary spectrum and it was available for use, or the railroad's technology does not require the use of spectrum, the railroad should indicate "N/A" in this table.

Based on AAR's request, FRA also added a comment box to the spectrum section so railroads can provide additional information or explanation.

C. Comments on Section 3—Quarterly Update on Major Installations

AAR, CSX, and Metra commented that FRA should delete the row entitled "Software for Train Management and Other Applications" from the table in Section 3 because software installation is not readily quantifiable. AAR specifically commented that "PTC software is versioned repeatedly over the course of the year with each release of defect remediation and improved functionality." Based on these concerns, FRA deleted the quantitative category for software installation and instead added a comment box for software, specifically requesting each railroad to "describe (1) the railroad's approach to installation of PTC software on its locomotive fleet, and (2) any issues the railroad is experiencing with installed versions of train management software (*e.g.*, reverting back to previous software versions due to errors in the current version)."

With respect to the locomotive hardware installation table in Section 3, AAR commented that the "number of antennas, event recorders, displays, and other components [including GPS receivers] tells the FRA nothing relevant about how close that railroad is to adding mission-capable locomotives to its fleet." Balancing FRA's need to monitor railroads' incremental implementation progress with the railroads' request that FRA reduce the reporting burden, FRA decided to modify the form by deleting the categories regarding antennas, GPS receivers, and secondary communications equipment. Moreover, FRA modified the row titles to clarify that a railroad should be reporting in terms of locomotives—for example, the railroad would report the quantity of locomotives with PTC displays installed, not the quantity of PTC displays installed.

The Utah Transit Authority commented that the progress report is geared only towards railroads installing the Interoperable Electronic Train Management System (I–ETMS) and, thus, it is difficult to reflect Utah Transit Authority's own progress implementing a PTC system because it states "N/A" for numerous categories, including spectrum, wayside interface units, and communication towers. FRA notes the PTCEI Act requires quantitative reporting for spectrum and these hardware categories. *See* 49 U.S.C. 20157(a)(2)(A)(iii)(III), (c)(1)(B), and (i). FRA added a general instruction to the cover page to clarify that railroads may indeed denote a section is not applicable if the particular hardware category does not apply to its technology. In footnotes 2 and 4 in the form, FRA also clarified that a railroad may elect to add categories or subcategories to the reporting form if it wants to provide more detail. Moreover, cognizant that each type of PTC system uses different hardware equipment, FRA chose to include "Transponder Readers" in the locomotive apparatus table in Section 3, which is a type of hardware used in non-I–ETMS types of PTC systems. Despite Utah Transit Authority's suggestion, FRA will not create a different progress report for each type of PTC system because there is not a definite number of PTC systems, various railroads may even implement a specific type of PTC system in different ways, and multiple reporting forms would be difficult to manage administratively.

The Fort Worth Transportation Authority commented the quantities of back office locations and dispatching locations installed should be only an annual, not quarterly, reporting requirement because these are large and complex installations that may take many months or years to build. More generally, BNSF and ASLRRA commented that neither back office locations nor "physical back office system equipment" (the statutory term) are possible to quantify in a meaningful way because most railroads have only one back office. Based on railroads' annual progress reports, however, FRA knows of at least one Class I railroad and one large passenger railroad that have more than one back office for PTC operations. To simplify the reporting burden, FRA has deleted the multi-faceted quantitative table regarding back office and dispatching locations and instead provided a series of more direct quantitative questions—*i.e.,* "How many physical back office locations are required for PTC operations, as reported in the PTCIP?" and "How many physical back office locations have been constructed with all necessary equipment installed?". Moreover, FRA is asking the same yes/no questions that it asked in the annual progress report—*i.e.,* "Are the Back Office Location(s) fully operable with PTC?" and "Are the Dispatching Location(s) fully operable with PTC?". And, FRA added a comment box for more information or explanation.

With respect to the Infrastructure—Wayside Installations table in Section 3, AAR commented that FRA should measure the hardware installation quantities system-wide, not by track segment, to reflect the railroad's implementation status more accurately. As requested, FRA modified this table to be system-wide, significantly reducing the reporting burden for railroads. In addition, FRA eliminated the quantitative questions regarding ground wiring and modified the row to ask only a yes/no question as in the annual progress report.

Finally, AAR commented that the "Year-to-Date Cumulative Total" is unclear because it could mean either the sum of the current year's progress or a cumulative for all prior years. To resolve the ambiguity, FRA modified the heading to instead state "Sum of Quarterly Totals" so railroads know that the column calls for the sum of the current year's progress. Also, for consistency with the annual progress report form, FRA added a "Cumulative Quantity Installed" column for the tables in Section 3.

D. Comments on Section 4—Installation/Track Segment Progress

AAR commented that FRA should add a "status" column for each row in Section 3 and eliminate the redundancy of Section 4. AAR believes the information could be better organized in one table and thus avoid the need for cross-referencing between the two tables during the review process. However, at the public meeting, AAR acknowledged the preferred modification would be for FRA to eliminate the track segment granularity from Section 3 and leave Section 4 as is. Accordingly, FRA removed the track-segment by track-segment aspect of Section 3, and did not modify Section 4.

Metra commented that, due to limited funding, it does not intend to create Geographic Information System (GIS) shapefiles to support the information request in Section 4 of the form, which stated "For all live segments, please provide GIS shapefile or corresponding data for segments put into operation." Instead, Metra commented that it could provide the geographic information in table format. FRA has decided to eliminate this particular reporting requirement from the quarterly form. In the annual progress report, FRA intends to clarify that a railroad can provide, for track segments that are operational and complete only, either GIS shapefiles *or* updated, geographical information sufficiently specific to allow FRA to maintain its GIS Database.

E. Comments on Section 5—Quarterly Update on Employee Training

Metra and AAR commented that the categories in the employee training section should align with the categories in 49 CFR 236.1041. Accordingly, FRA modified the employee categories in the quarterly form to correspond with the regulations, just as it did in the annual form, based on AAR's similar comment. The Fort Worth Transportation Authority also commented that railroads should have to provide employee training updates only annually, not quarterly, and BNSF commented it is difficult to accurately quantify employee training due to hiring, firing, retiring, and so forth. Although FRA acknowledges there might be a certain level of fluidity to employee training, FRA will nonetheless continue to ask for a quantitative update for employee training consistent with the railroad's revised PTCIP.

For consistency with the annual progress report form, FRA added a "Cumulative # of Employees Trained" column to the table in Section 5 and provided a comment box.

F. Comments on Section 6—Quarterly Update on Interoperability Progress

No comments were received on the interoperability section of the quarterly progress report form. However, FRA notes it modified this section to align with the revisions it made to this corresponding section in the annual progress report.

G. Comments on Burden Estimate, Applicability, and Formatting

AAR commented that its member railroads estimate it will take approximately 40 hours to complete the quarterly progress report form, as opposed to the 1.5 hours that FRA estimated. FRA notes that the 1.57-hour estimate is an average for all railroads. FRA estimated that the quarterly reporting burden is 3 hours for Class I and large passenger railroads, 2 hours for Class II and medium passenger railroads, and .5 hours for Class III, terminal, and small passenger railroads. These estimates take into account that railroads have already completed and provided to FRA the Annual PTC Progress Report, which requests similar types of information as the form for the Quarterly PTC Progress Report, but with more sections. FRA maintains that the average reporting burden for the quarterly form is 1.57 hours, especially as FRA has eliminated portions of the quarterly form initially proposed on March 7, 2016. 81 FR 11878.

Both ASLRRA and the Tri-County Metropolitan Transportation District of Oregon requested clarification about whether only host railroads must submit the quarterly progress reports or whether the reporting requirement also applies to tenant railroads. FRA notes that the annual reporting the PTCEI Act mandated applies to any entity subject to 49 U.S.C. 20157(a), and the scope of this quarterly reporting is the same. A tenant railroad may coordinate with its host railroad to ensure the host railroad captures the tenant railroad's implementation progress in its progress reports.

Once OMB approves this information collection, FRA will provide the Quarterly PTC Progress Report Form to railroads in fillable PDF and Excel formats, which would be available for download on *https://www.fra.dot.gov/eLib/details/L17365.* For purposes of internal data tracking and analysis, FRA requests that each railroad submit its report in the native format—*i.e.,* if the railroad uses the FRA-provided Excel document, the railroad should submit the report in Excel format. FRA has provided the industry with prototypes of each format, and the public may submit comments on formatting preferences to OMB's Office of Information and Regulatory Affairs (Attn: FRA OMB Desk Officer).

III. Overview of Information Collection

The associated collection of information is summarized below.

Title: Quarterly Positive Train Control Progress Report Form.

Reporting Burden:

Quarterly PTC progress report	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
Form FRA F 6180.165	41 Railroads	164 Reports/Forms	1.573 hours	258 hours

Form Number: FRA F 6180.165.

Respondent Universe: 41 Railroads.

Frequency of Submission: On occasion.

Total Estimated Responses for New Quarterly PTC Progress Report Form: 164.

Total Estimated Responses for Entire Information Collection: 147,776.

Total Estimated Annual Burden for New PTC Quarterly Progress Report Forms: 258 hours.

Total Estimated Burden for Entire Information Collection: 3,122,817.

Status: Regular Review.

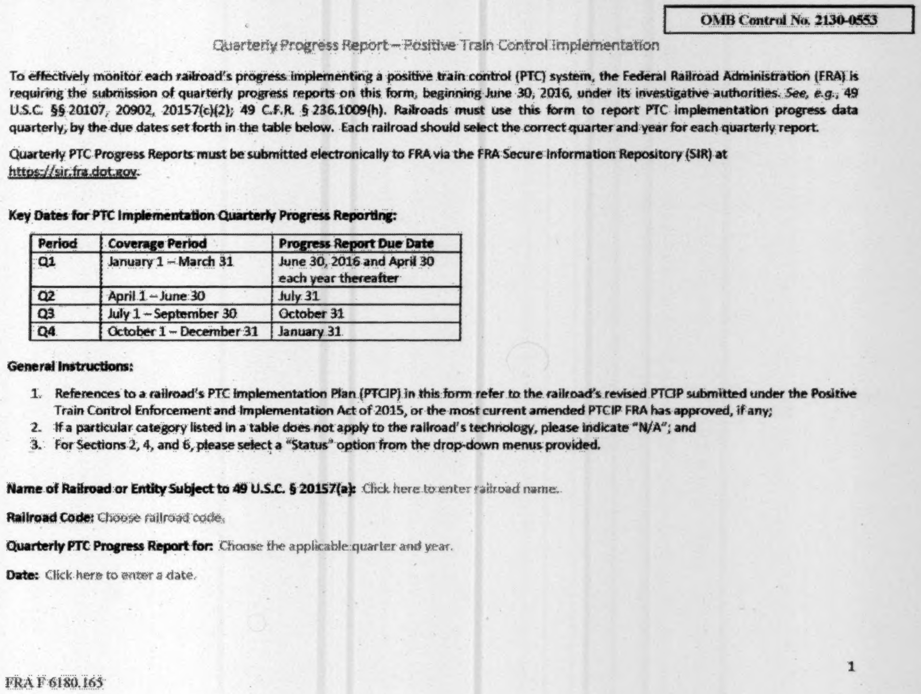
Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520, 49 U.S.C. 20157(c)(2); *see also* 49 U.S.C. 20107, 20902; 49 CFR 236.1009(h).

Issued in Washington, DC, on April 29, 2016.

Corey Hill,

Executive Director.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

To effectively monitor each railroad's progress implementing a positive train control (PTC) system, the Federal Railroad Administration (FRA) is requiring the submission of quarterly progress reports on this form, beginning June 30, 2016, under its investigative authorities. *See, e.g.*, 49 U.S.C. §§ 20107, 20902, 20157(c)(2); 49 C.F.R. § 236.1009(h). Railroads must use this form to report PTC implementation progress data quarterly, by the due dates set forth in the table below. Each railroad should select the correct quarter and year for each quarterly report.

Quarterly PTC Progress Reports must be submitted electronically to FRA via the FRA Secure Information Repository (SIR) at https://sir.fra.dot.gov.

Key Dates for PTC Implementation Quarterly Progress Reporting:

Period	Coverage Period	Progress Report Due Date
Q1	January 1 – March 31	June 30, 2016 and April 30 each year thereafter
Q2	April 1 – June 30	July 31
Q3	July 1 – September 30	October 31
Q4	October 1 – December 31	January 31

General Instructions:

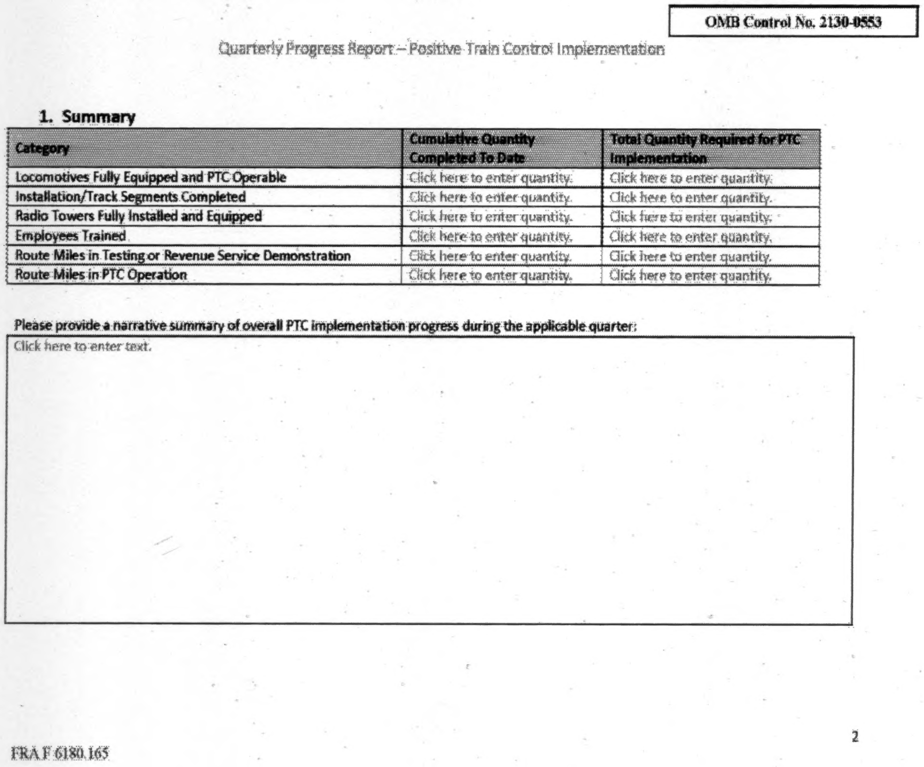
1. References to a railroad's PTC Implementation Plan (PTCIP) in this form refer to the railroad's revised PTCIP submitted under the Positive Train Control Enforcement and Implementation Act of 2015, or the most current amended PTCIP FRA has approved, if any;
2. If a particular category listed in a table does not apply to the railroad's technology, please indicate "N/A"; and
3. For Sections 2, 4, and 6, please select a "Status" option from the drop-down menus provided.

Name of Railroad or Entity Subject to 49 U.S.C. § 20157(a): Click here to enter railroad name.

Railroad Code: Choose railroad code.

Quarterly PTC Progress Report for: Choose the applicable quarter and year.

Date: Click here to enter a date.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

1. Summary

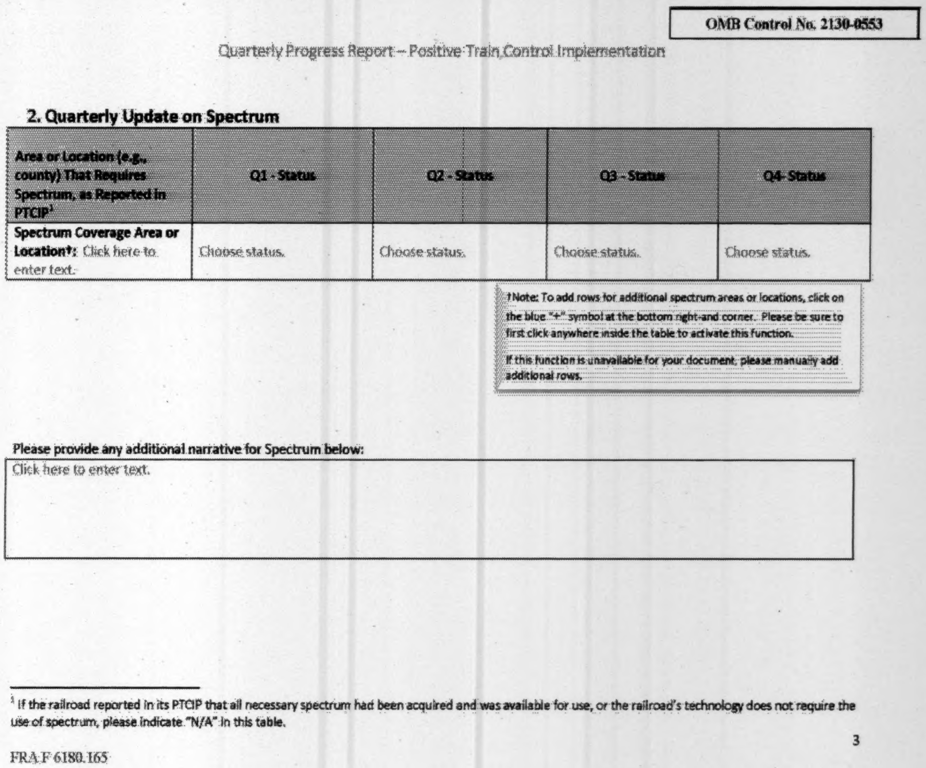
Category	Cumulative Quantity Completed To Date	Total Quantity Required for PTC Implementation
Locomotives Fully Equipped and PTC Operable	Click here to enter quantity.	Click here to enter quantity.
Installation/Track Segments Completed	Click here to enter quantity.	Click here to enter quantity.
Radio Towers Fully Installed and Equipped	Click here to enter quantity.	Click here to enter quantity.
Employees Trained	Click here to enter quantity.	Click here to enter quantity.
Route Miles in Testing or Revenue Service Demonstration	Click here to enter quantity.	Click here to enter quantity.
Route Miles in PTC Operation	Click here to enter quantity.	Click here to enter quantity.

Please provide a narrative summary of overall PTC implementation progress during the applicable quarter:

Click here to enter text.

FRA F 6180.165

2



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

2. Quarterly Update on Spectrum

Area or Location (e.g., county) That Requires Spectrum, as Reported in PTCIP[1]	**Q1 - Status**	**Q2 - Status**	**Q3 - Status**	**Q4- Status**
Spectrum Coverage Area or Location†: Click here to enter text.	Choose status.	Choose status.	Choose status.	Choose status.

†Note: To add rows for additional spectrum areas or locations, click on the blue "+" symbol at the bottom right-and corner. Please be sure to first click anywhere inside the table to activate this function.

If this function is unavailable for your document, please manually add additional rows.

Please provide any additional narrative for Spectrum below:

Click here to enter text.

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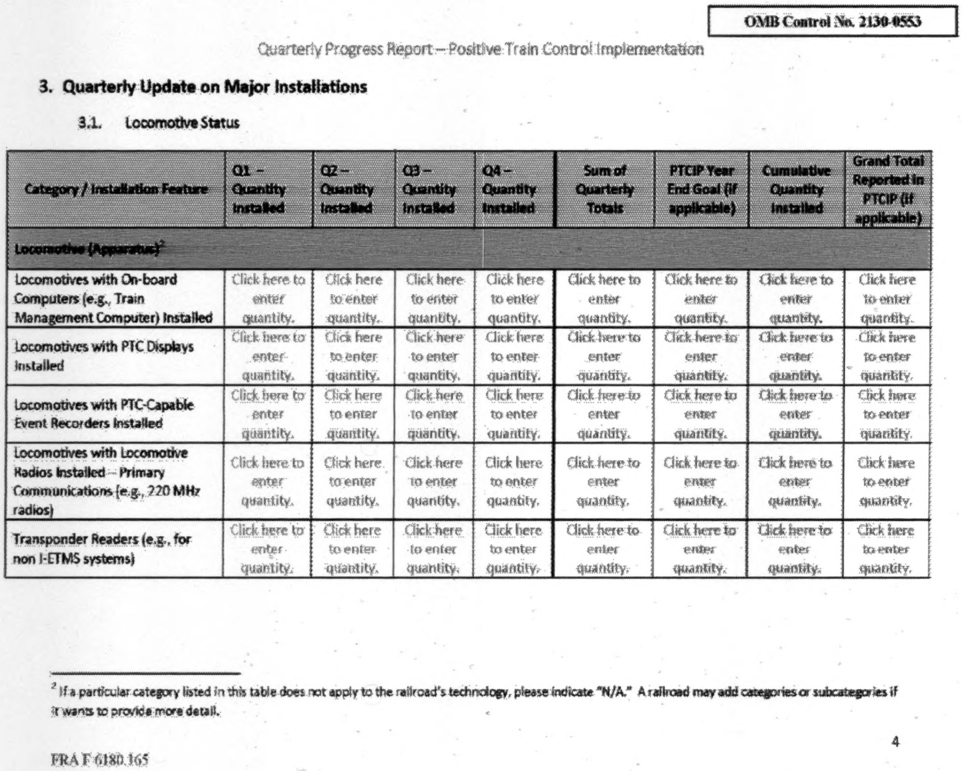
[1] If the railroad reported in its PTCIP that all necessary spectrum had been acquired and was available for use, or the railroad's technology does not require the use of spectrum, please indicate "N/A" in this table.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

3. Quarterly Update on Major Installations

3.1. Locomotive Status

Category / Installation Feature	Q1 – Quantity Installed	Q2 – Quantity Installed	Q3 – Quantity Installed	Q4 – Quantity Installed	Sum of Quarterly Totals	PTCIP Year End Goal (if applicable)	Cumulative Quantity Installed	Grand Total Reported in PTCIP (if applicable)
Locomotive (Apparatus)[2]								
Locomotives with On-board Computers (e.g., Train Management Computer) Installed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Locomotives with PTC Displays Installed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Locomotives with PTC-Capable Event Recorders Installed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Locomotives with Locomotive Radios Installed – Primary Communications (e.g., 220 MHz radios)	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Transponder Readers (e.g., for non I-ETMS systems)	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.

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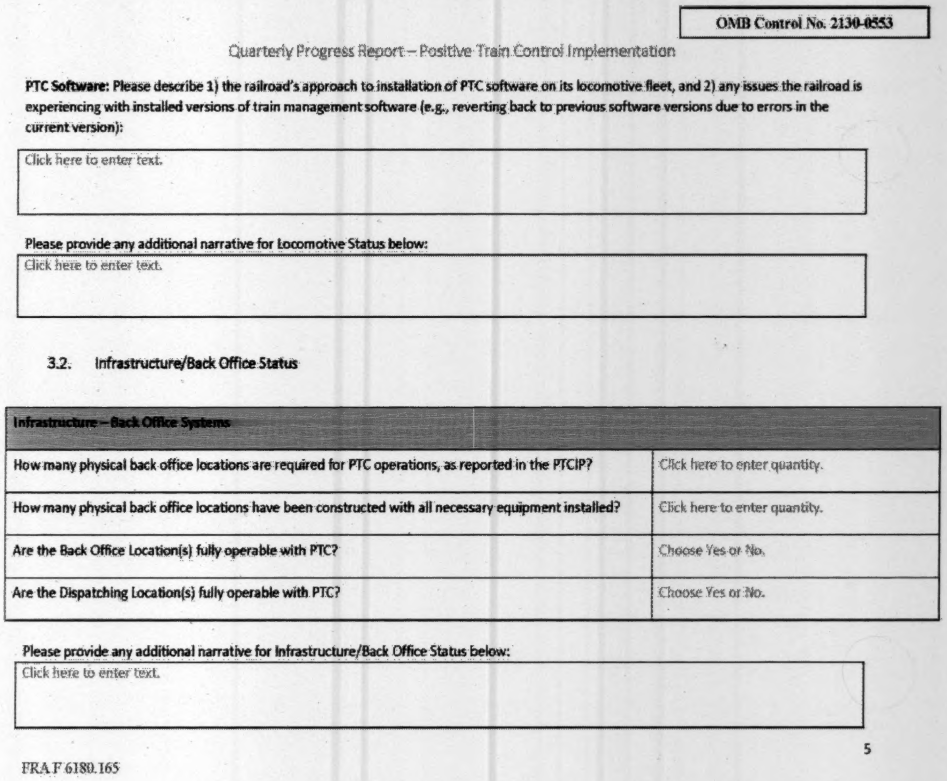
[2] If a particular category listed in this table does not apply to the railroad's technology, please indicate "N/A." A railroad may add categories or subcategories if it wants to provide more detail.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

PTC Software: Please describe 1) the railroad's approach to installation of PTC software on its locomotive fleet, and 2) any issues the railroad is experiencing with installed versions of train management software (e.g., reverting back to previous software versions due to errors in the current version):

Click here to enter text.

Please provide any additional narrative for Locomotive Status below:

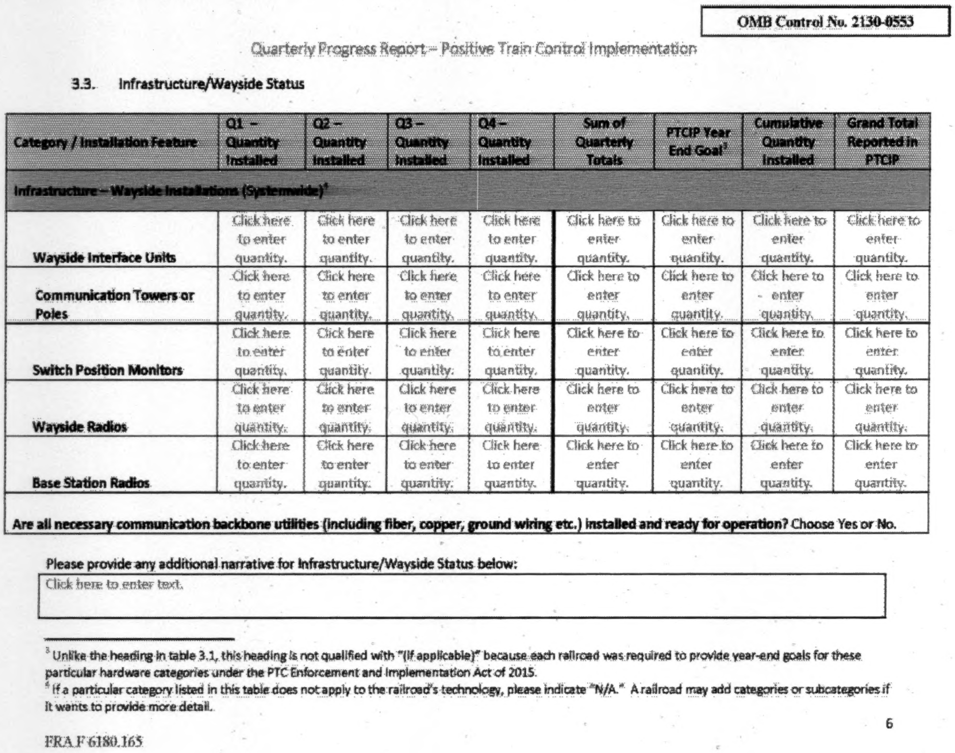
Click here to enter text.

3.2. Infrastructure/Back Office Status

Infrastructure – Back Office Systems	
How many physical back office locations are required for PTC operations, as reported in the PTCIP?	Click here to enter quantity.
How many physical back office locations have been constructed with all necessary equipment installed?	Click here to enter quantity.
Are the Back Office Location(s) fully operable with PTC?	Choose Yes or No.
Are the Dispatching Location(s) fully operable with PTC?	Choose Yes or No.

Please provide any additional narrative for Infrastructure/Back Office Status below:

Click here to enter text.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

3.3. Infrastructure/Wayside Status

Category / Installation Feature	Q1 – Quantity Installed	Q2 – Quantity Installed	Q3 – Quantity Installed	Q4 – Quantity Installed	Sum of Quarterly Totals	PTCIP Year End Goal[3]	Cumulative Quantity Installed	Grand Total Reported in PTCIP
Infrastructure – Wayside Installations (Systemwide)[4]								
Wayside Interface Units	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Communication Towers or Poles	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Switch Position Monitors	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Wayside Radios	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Base Station Radios	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Are all necessary communication backbone utilities (including fiber, copper, ground wiring etc.) installed and ready for operation? Choose Yes or No.								

Please provide any additional narrative for Infrastructure/Wayside Status below:

Click here to enter text.

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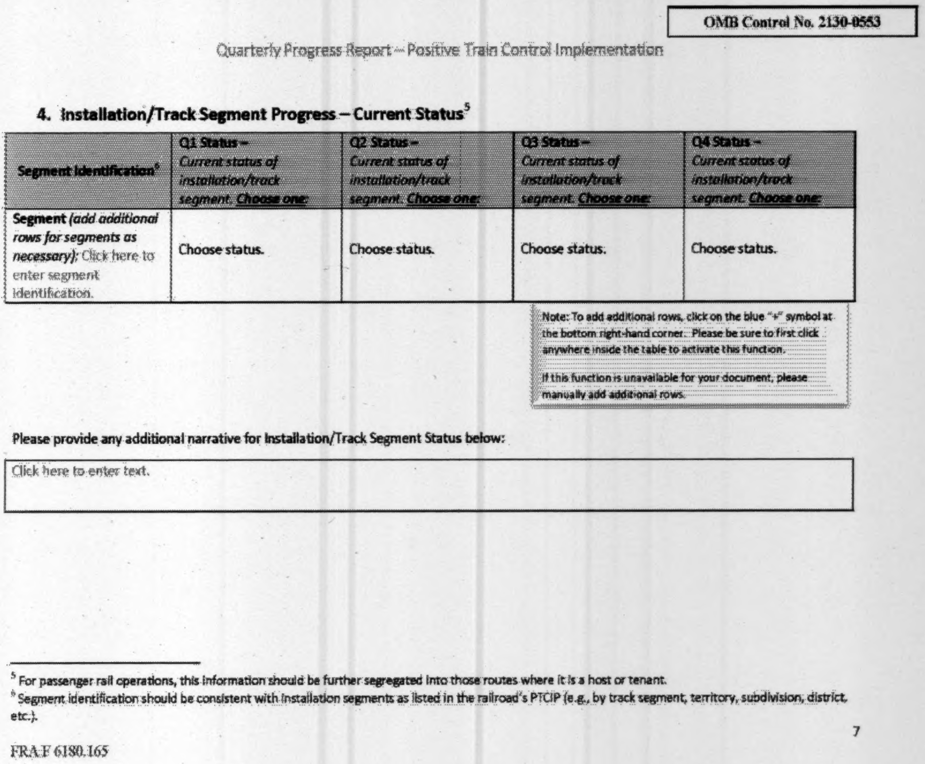
[3] Unlike the heading in table 3.1, this heading is not qualified with "(If applicable)" because each railroad was required to provide year-end goals for these particular hardware categories under the PTC Enforcement and Implementation Act of 2015.

[4] If a particular category listed in this table does not apply to the railroad's technology, please indicate "N/A." A railroad may add categories or subcategories if it wants to provide more detail.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

4. Installation/Track Segment Progress – Current Status[5]

Segment Identification[6]	**Q1 Status –** *Current status of installation/track segment.* ***Choose one:***	**Q2 Status –** *Current status of installation/track segment.* ***Choose one:***	**Q3 Status –** *Current status of installation/track segment.* ***Choose one:***	**Q4 Status –** *Current status of installation/track segment.* ***Choose one:***
Segment *(add additional rows for segments as necessary);* Click here to enter segment identification.	Choose status.	Choose status.	Choose status.	Choose status.

Note: To add additional rows, click on the blue "+" symbol at the bottom right-hand corner. Please be sure to first click anywhere inside the table to activate this function.

If this function is unavailable for your document, please manually add additional rows.

Please provide any additional narrative for Installation/Track Segment Status below:

Click here to enter text.

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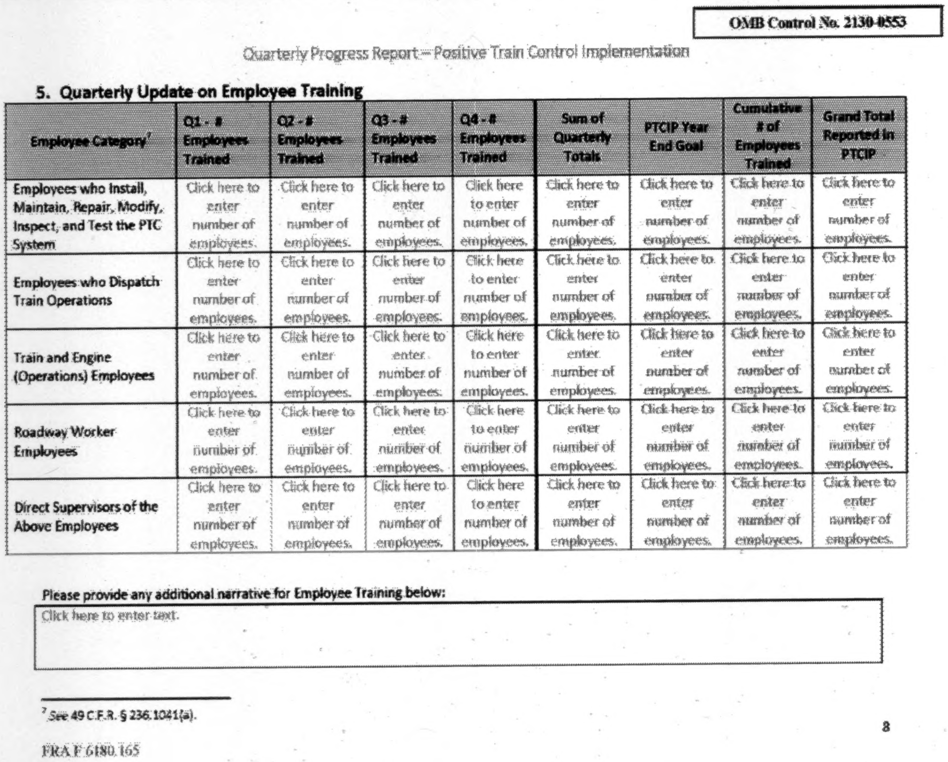
[5] For passenger rail operations, this information should be further segregated into those routes where it is a host or tenant.

[6] Segment identification should be consistent with installation segments as listed in the railroad's PTCIP (e.g., by track segment, territory, subdivision, district, etc.).



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

5. Quarterly Update on Employee Training

Employee Category[7]	Q1 - # Employees Trained	Q2 - # Employees Trained	Q3 - # Employees Trained	Q4 - # Employees Trained	Sum of Quarterly Totals	PTCIP Year End Goal	Cumulative # of Employees Trained	Grand Total Reported in PTCIP
Employees who Install, Maintain, Repair, Modify, Inspect, and Test the PTC System	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Employees who Dispatch Train Operations	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Train and Engine (Operations) Employees	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Roadway Worker Employees	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Direct Supervisors of the Above Employees	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.

Please provide any additional narrative for Employee Training below:

Click here to enter text.

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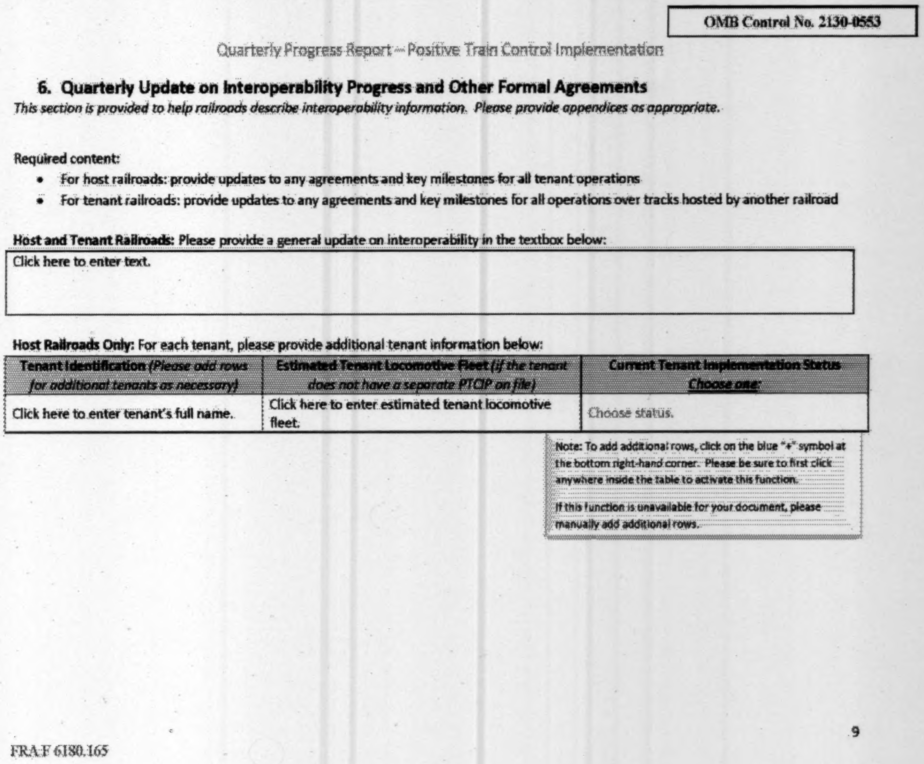
[7] *See* 49 C.F.R. § 236.1041(a).



OMB Control No. 2130-0553

6. Quarterly Update on Interoperability Progress and Other Formal Agreements

This section is provided to help railroads describe interoperability information. Please provide appendices as appropriate.

Required content:

- For host railroads: provide updates to any agreements and key milestones for all tenant operations
- For tenant railroads: provide updates to any agreements and key milestones for all operations over tracks hosted by another railroad

Host and Tenant Railroads: Please provide a general update on interoperability in the textbox below:

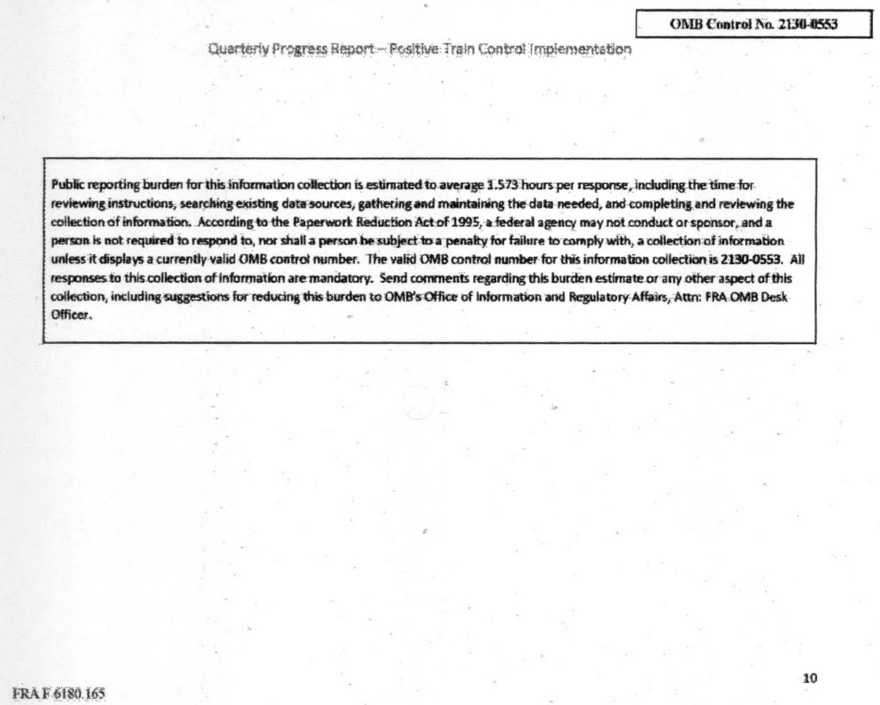
Click here to enter text.

Host Railroads Only: For each tenant, please provide additional tenant information below:

Tenant Identification *(Please add rows for additional tenants as necessary)*	**Estimated Tenant Locomotive Fleet** *(if the tenant does not have a separate PTCIP on file)*	**Current Tenant Implementation Status** ***Choose one:***
Click here to enter tenant's full name.	Click here to enter estimated tenant locomotive fleet.	Choose status.

Note: To add additional rows, click on the blue "+" symbol at the bottom right-hand corner. Please be sure to first click anywhere inside the table to activate this function.

If this function is unavailable for your document, please manually add additional rows.



OMB Control No. 2130-0553

Quarterly Progress Report – Positive Train Control Implementation

Public reporting burden for this information collection is estimated to average 1.573 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. According to the Paperwork Reduction Act of 1995, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information unless it displays a currently valid OMB control number. The valid OMB control number for this information collection is 2130-0553. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection, including suggestions for reducing this burden to OMB's Office of Information and Regulatory Affairs, Attn: FRA OMB Desk Officer.

FRA F 6180.165

10

[FR Doc. 2016–10831 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2000–7257, Notice Number 8]

Northeast Corridor Safety Advisory Committee; Notice of Meeting

AGENCY: Federal Railroad Administration (FRA), Department of Transportation.

ACTION: Announcement of Northeast Corridor Safety Advisory Committee (NECSC) meeting.

SUMMARY: FRA announces the sixth meeting of the NECSC, a Federal Advisory Committee mandated by section 212 of the Passenger Rail Investment and Improvement Act of 2008 (PRIIA). The NECSC is composed of stakeholders operating on the Northeast Corridor (NEC), and its purpose is to provide annual recommendations to the U.S. Secretary of Transportation. NECSC meeting topics will include the following: Maintenance-of-way fatigue, presentations on the NEC's future and NEC construction projects, Tier III passenger equipment rulemaking, the Confidential Close Call Reporting System (C^{3}RS), Amtrak 160 mph waiver requests, split rail derails on track leading to the NEC, and a general discussion of safety issues.

DATES: The NECSC meeting is scheduled to begin at 9:30 a.m. on Wednesday, May 25, 2016, and will adjourn by 4:30 p.m.

ADDRESSES: The NECSC meeting will be held at the National Housing Center located at 1201 15th Street NW., Washington, DC 20005. The meeting is open to the public on a first-come, first-served basis and is accessible to individuals with disabilities. Sign and oral interpretation can be made available if requested 10 calendar days before the meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Woolverton, RSAC Administrative Officer/Coordinator, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6212; or Mr. Robert C. Lauby, Associate Administrator for Railroad Safety and Chief Safety Officer, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6474.

SUPPLEMENTARY INFORMATION: The NECSC is mandated by a statutory provision in section 212 of the PRIIA (codified at 49 U.S.C. 24905(f)). The NECSC is chartered by the U.S. Secretary of Transportation, and is an official Federal Advisory Committee established in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. title 5—Appendix.

Issued in Washington, DC on May 3, 2016.

Patrick T. Warren,

Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 2016–10774 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Environmental Impact Statement for the California High Speed Rail System San Francisco to San Jose Section, CA

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS).

SUMMARY: Through this NOI, FRA announces its intent to jointly prepare an Environmental Impact Report (EIR) and Environmental Impact Statement (EIS) with the California High-Speed Rail Authority (Authority) for the San Francisco to San Jose Section of the California High-Speed Rail (HSR) System, Blended System Project (Blended System Project or Project). FRA invites the public and all interested parties to provide comments on the scope of the EIR/EIS, including the proposed purpose and need, the alternatives to consider, potential environmental impacts of concern, and methodologies for analysis of impacts. Through this NOI, FRA also rescinds its December 2008 NOI for the San Francisco to San Jose Section.

FRA and the Authority will develop the EIR/EIS in compliance with the California Environmental Quality Act (CEQA) and the National Environmental Policy Act of 1969 (NEPA). FRA and the Authority will hold scoping meetings and outreach activities as part of the NEPA/CEQA process. Federal cooperating agencies for the EIR/EIS are the Surface Transportation Board (STB) and the U.S. Army Corps of Engineers (USACE).

DATES: Written comments on the scope of the San Francisco to San Jose Section EIR/EIS must be provided to the Authority by June 8, 2016.

Public scoping meetings are scheduled in May 2016: FRA and the Authority will hold the scoping meetings between 5:00 p.m. and 8:00 p.m. at the following dates:

- *San Francisco:* Monday, May 23, 2016.
- *San Mateo:* Tuesday, May 24, 2016.
- *Mountain View:* Wednesday, May 25, 2016.

The Authority will make scoping materials and information concerning the scoping meetings available on the Authority's Web site: *http://hsr.ca.gov/Programs/Statewide_Rail_Modernization/project_sections/sanfrancisco_sanjose.html.*

ADDRESSES: You can send written comments on the scope to Mr. Mark McLoughlin, Director of Environmental Services, Attention: San Francisco to San Jose Section EIR/EIS, California High-Speed Rail Authority, 770 L Street, Suite 1160, Sacramento, CA 95814, or via email with subject line "San Francisco to San Jose Section EIR/EIS" to: *comments@hsr.ca.gov.*

You may provide comments orally or in writing at scoping meetings. FRA and the Authority will hold the scoping meetings between 5:00 p.m. and 8:00 p.m. at the following locations:

- *San Francisco:* University of California, San Francisco Mission Bay, 11500 Owens Street, San Francisco, CA 94158.
- *San Mateo:* San Mateo Marriott, 1770 South Amphlett Boulevard, San Mateo, CA 94402.
- *Mountain View:* SFV Lodge, 361 Villa Street, Mountain View, CA 94041.

FOR FURTHER INFORMATION CONTACT: Ms. Stephanie Perez, Environmental Protection Specialist, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE., (Mail Stop 20), Washington, DC 20590; Telephone: (202) 493–0388, email: *stephanie.perez@dot.gov,* or Mr. Guy Preston, Regional Delivery Manager, California High Speed Rail Authority, 100 Paseo de San Antonio, San Jose, CA 95113, Telephone: (408) 277–1091 or *sanfrancisco_sanjose@hsr.ca.gov.*

SUPPLEMENTARY INFORMATION: FRA is an operating administration of the U.S. Department of Transportation and is responsible for overseeing the safety of railroad operations, including the safety of any proposed high-speed ground transportation system. FRA is also authorized to provide, subject to appropriations, funding for high-speed and intercity passenger rail projects and is also authorized to provide loans and other financial support for railroad investments. FRA is conducting this review under NEPA because it may provide funding or financing for this project in the future. STB and USACE are Federal cooperating agencies on the EIS. STB has approval authority under

49 U.S.C. 10901 over the construction and operation of the proposed California HSR System. USACE has jurisdiction under Section 404 of the Clean Water Act.

The Authority was established in 1996 and is authorized and directed by statute to undertake the planning and development of a proposed statewide HSR network fully coordinated with other public transportation services. In 2005, the Authority and FRA completed a Final Program EIR/EIS for the Proposed California HSR System (Statewide Program EIR/EIS), as the first phase of a tiered environmental review process. The Statewide Program EIR/EIS analyzed a No Project/No Action Alternative; a Modal Alternative involving expanding freeways, airports, and conventional rail systems; and a HSR alternative using electric propulsion and steel-wheel-on-steel-rail vehicles capable of operating speeds of 220 mph on fully grade separated rail alignments with state-of-the-art safety, signaling, and communication systems. The Authority certified the Statewide Program EIR under CEQA and approved the proposed HSR System, and FRA issued a Record of Decision under NEPA on the Statewide Program EIS.

In approving the Statewide Program EIR/EIS, FRA and the Authority selected the HSR Alternative for intercity travel in California between the major metropolitan centers of Sacramento and the San Francisco Bay Area in the north, through the Central Valley, to Los Angeles and San Diego in the south. The Authority and FRA also selected certain corridors/general alignments and general station locations for further study; committed to mitigation strategies and design practices; and specified further measures to guide the development of the HSR system at the site-specific project level of environmental review to avoid and minimize potential adverse environmental impacts. FRA and the Authority did not select corridors or station locations between the Central Valley and the Bay Area in 2005. Rather, they decided to prepare a second program EIR/EIS for that area.

In 2008, the Authority and FRA further evaluated alignments and station locations within the broad corridor between and including the Altamont Pass and the Pacheco Pass to connect the Bay Area and Central Valley portions of the HSR system in the Bay Area to the Central Valley High-Speed Train Program EIR/EIS. Based on that EIR/EIS, the Authority and FRA selected the Pacheco Pass—San Francisco and San Jose termini network alternative, including corridor alignments and station location options. The selected corridor alignment uses the Caltrain rail right-of-way, between San Francisco and San Jose along the San Francisco Peninsula, and the Pacheco Pass via Henry Miller Road, between San Jose and the Central Valley.

In December 2008, the Authority and FRA respectively issued a notice of preparation and notice of intent to prepare an EIR/EIS for the project-level San Francisco to San Jose Section of the proposed California HSR System. In 2009, the Authority and FRA completed project scoping and provided the public with alternatives screening documents. These alternatives screening documents were for a rail corridor based on an entirely grade separated a four-track system between San Francisco and San Jose where HSR would share tracks with Caltrain express commuter trains. Communities along the Caltrain corridor expressed concerns with this proposal because of the perceived magnitude of impacts to environmental and community resources. In response to these concerns, the Authority suspended further work on the EIR/EIS in mid-2011 to consider blending the HSR and Caltrain operations within a smaller project footprint. In November 2011, the Authority proposed blended operations for the HSR section between San Francisco and San Jose, which would still provide HSR and Caltrain service between the two cities without requiring a four-track system for the Project.

The San Francisco to San Jose Section EIR/EIS will describe the Blended System Project in detail, identify site-specific environmental impacts from construction, operation, and maintenance of the Blended System Project; identify specific mitigation measures to address those impacts; and incorporate appropriate design practices to avoid and minimize potential adverse environmental impacts. The EIR/EIS will describe the site characteristics, size, nature, and timing of the proposed action as a basis for determining whether the impacts are potentially significant and whether impacts can be avoided, minimized, or mitigated. The Authority will provide information and documents regarding this EIR/EIS on the Authority's Web site: *http://www.hsr.ca.gov.*

The San Francisco to San Jose Section EIR/EIS will tier from, and build upon, the Statewide Program EIR/EIS and the Bay Area to Central Valley HSR Program EIR/EIS consistent with Council on Environmental Quality (CEQ) regulations, (40 CFR 1508.28) and State CEQA Guidelines (14 California Code of Regulations 15168(b)).

In addition to the NEPA and CEQA process, the Authority is required by law to publish a Business Plan, updated every two years, which includes a description of service type, chronology of statewide construction, estimate of capital costs per segment, operating and maintenance costs, environmental review schedule, and discussion of public and private funding availability. The Draft 2016 Business Plan, which the Authority released in February, describes a phased implementation of the statewide HSR system. The Draft 2016 Plan prioritizes construction between San Jose and the Central Valley, but also emphasizes the importance of extending HSR service from San Francisco to San Jose as soon as possible.

Purpose and Need

The purpose of the proposed HSR system is to provide a new mode of high-speed intercity travel that would link major metropolitan areas of the state; interface with international airports, mass transit, and highways; and provide added capacity to meet increases in intercity travel demand in California in a manner sensitive to and protective of California's unique natural resources. The need for a HSR system is directly related to the expected growth in population, and increases in intercity travel demand in California over the next twenty years and beyond. With the growth in travel demand, there will be an increase in travel delays arising from the growing congestion on California's highways and at airports. In addition, there will be negative effects on the economy, quality of life, and air quality in and around California's metropolitan areas from a transportation system that will become less reliable as travel demand increases. The intercity highway system, commercial airports, and conventional passenger rail serving the intercity travel market are currently operating at or near capacity, and will require large public investments for maintenance and expansion to meet existing demand and future growth. The proposed HSR System is designed to address some of the social, economic, and environmental problems associated with transportation congestion in California.

The San Francisco to San Jose Section meets this purpose and need by:

- Connecting the San Francisco Bay Area to the rest of the statewide HSR system, including the Central Valley and Southern California;
- Incorporating HSR into the intermodal hubs at San Francisco, Millbrae and San Jose, thereby providing interfaces with airports (San

Francisco International Airport and Norman J. Mineta San Jose International Airport), mass transit (BART, Caltrain, Capitol Corridor, Amtrak, and light-rail and bus services), and highways, resulting in local and regional transportation hubs;

- Serving a large base of riders in the densely populated San Francisco and San Jose metropolitan areas; and
- Reaching station locations with existing and planned transit oriented development potential.

Alternatives

The San Francisco to San Jose Section EIR/EIS will consider a No Action or No Project Alternative and one or more HSR Alternatives for the San Francisco to San Jose corridor. The San Francisco to San Jose Section of the HSR system would connect to the San Jose to Merced Section at Diridon Station, which would extend HSR service from the San Francisco Bay Area to the Central Valley and Southern California.

No Action Alternative

The No Action Alternative (No Project or No Build) represents conditions in the San Francisco to San Jose corridor as they exist in 2016, and as they would exist in future years based on projected growth, programmed and funded improvements to the intercity transportation system, and other reasonably foreseeable projects through the implementation of Phase 1 operations in 2029, and a future year of operation in 2040. The No Action alternative takes into account the following sources of information: State Transportation Improvement Program; Regional Transportation Plans for all modes of travel; airport plans; intercity passenger rail plans; and city and county plans.

HSR Blended System Alternative(s)

The Blended System Project would follow the Caltrain right-of-way from San Francisco to San Jose. It would utilize existing and in-progress infrastructure Caltrain developed for its electrification project, but require construction in addition to electrification. The Blended System Project is anticipated to include the following, subject to continued planning and engineering following the scoping/outreach process:

New and/or Upgraded Infrastructure

- Track improvements to support higher speeds, including upgrades of tracks, trackbeds, ties, interlockings, and possible curve straightening;
- At least one passing track, with potential alternative locations for the passing track;
- One terminal storage maintenance facility, with potential alternative locations;
- Improvements to existing bridges necessary to accommodate mixed traffic;
- Potential grade separations necessary to support blended operations; and
- Installation of quad gates at remaining grade crossings.

Proposed Operations

- High-speed rail vehicles operating over mostly the same tracks between San Francisco and San Jose;
- Speeds of up to 110 miles per hour; and
- Operations plan that would allow for up to 4 HSR vehicles per hour/per direction in the peak period.

Upgrades to Existing Stations

- Raised and straightened platforms, platform screens (or other safety features) and passenger facilities at 4th & King, Millbrae and Diridon stations.

Transbay Transit Center (TTC) and Downtown Extension DTX projects

- The Authority proposes its Blended System Project will reach the TTC in San Francisco via the planned 1.3-mile extension of passenger rail track from the current terminus at the Caltrain 4th and King station.
- The Transbay Joint Powers Authority is the state lead agency for both projects, which have been the subject of separate environmental review.
- The TTC is currently under construction. The DTX is not yet under construction.
- Both projects will be addressed in the San Francisco to San Jose Section EIR/EIS.

During the Programmatic review phase, FRA and the Authority selected the Transbay Transit Center as the station location in the city of San Francisco. However, the Authority anticipates that the 4th and King Station would operate as an interim station until completion of the Transbay Transit Center which the Transbay Joint Powers Authority is constructing and funding. Other HSR stations would be located in the city of Millbrae at the existing Millbrae BART/Caltrain Station, and in the city of San Jose at the existing Diridon Station. FRA and Authority selected these locations through the Bay Area to Central Valley HSR Final Program EIR/EIS.

Probable Effects

The EIR/EIS will evaluate and document the effects of the proposed project on the physical, human, and natural environment. FRA and the Authority will continue the tiered evaluation of all potentially significant environmental, social, and economic impacts of the construction and operation of the HSR system. The San Francisco to San Jose EIR/EIS will address appropriate resource areas including: Transportation, including impacts on existing passenger and freight rail tenants; safety and security; land use and zoning; land acquisition, displacements, and relocations; cumulative and secondary impacts; cultural resource impacts, including impacts on historical and archaeological resources; parklands/recreation areas; neighborhood compatibility and environmental justice; geology and paleontology impacts; natural resource impacts including air quality, wetlands, water resources, noise and vibration, energy, wildlife and ecosystems, including endangered species, energy and hazardous materials. The EIR/EIS will also identify and evaluate measures to avoid, minimize, and mitigate adverse impacts.

The San Francisco to San Jose Section EIR/EIS will be prepared consistent with FRA's Procedures for Considering Environmental Impacts (64 FR 28545, May 26, 1999) and the CEQ's regulations implementing NEPA at 40 CFR parts 1500–1508. The San Francisco to San Jose Section EIR/EIS also will address, as necessary, other applicable statutes, regulations, and executive orders, including the Clean Air Act, Section 106 of the National Historic Preservation Act (Section 106) of 1966, Section 4(f) of the Department of Transportation Act, the Endangered Species Act, and Executive Order 12898 on Environmental Justice.

FRA funding or approval of the San Francisco to San Jose Section would be a Federal undertaking with the potential to affect historic properties. As such, it is subject to the requirements of Section 106. Consistent with the Advisory Council on Historic Preservation's (ACHP) regulations implementing Section 106, FRA intends to coordinate compliance with Section 106 of this Act with the preparation of the San Francisco to San Jose Section EIR/EIS, beginning with the identification of consulting parties in a manner consistent with the standards set out in 36 CFR 800.8. Under the Programmatic Agreement among FRA, ACHP, the California State Historic Preservation Officer, and the Authority, FRA and the Authority will conduct a phased review of effects on historic properties consistent with 36 CFR 800.4(b)(2). FRA invites the public and interested parties to provide comments on the potential effects of the proposed alternatives on historic properties within the San Francisco to San Jose Section. In response to this NOI, a member of the public or other interested party may also request to participate in the Section 106 process as a consulting party under 36 CFR part 800.

Scoping and Comments

FRA encourages broad participation in the EIS process during scoping and review of the resulting environmental documents. FRA invites Native American Tribes, interested agencies, and the public at large to participate in the scoping process to ensure the EIR/EIS addresses the full range of issues related to the proposed action and reasonable alternatives, and that all significant issues are identified. FRA requests that any public agency having jurisdiction over an aspect of the Project identify the applicable permit and environmental review requirements of the agency and the scope and content of the environmental information germane to the agency's jurisdiction over the Project. Public agencies are requested to advise FRA if they anticipate taking a major action in connection with the proposed project and if they wish to participate as a cooperating agency for the San Francisco to San Jose Section EIR/EIS.

FRA and the Authority have scheduled public scoping meetings which are an important component of the scoping process for both the State and Federal environmental review. The Authority will advertise the scoping meetings described in this NOI locally and be included with any additional public notification.

Issued in Washington, DC, on May 4, 2016.

Jamie Rennert,

Director, Office of Program Delivery.

[FR Doc. 2016–10959 Filed 5–6–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. 2016–0021]

Notice of Request for the Extension of a Currently Approved Information Collection

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to renew the following information collection:

49 U.S.C. Section 5337 State of Good Repair Program

OMB Control No.: 2132–0577.

49 U.S.C. Section 5337, the State of Good Repair Grants Program was authorized by Moving Ahead for Progress in the 21st Century (MAP–21). It was reauthorized under the Fixing America's Surface Transportation (FAST) Act Section 3015. This program authorizes the Secretary of Transportation to make grants to designated recipients to maintain, replace, and rehabilitate high intensity fixed guideway systems and high intensity motorbus systems. Eligible recipients include state and local government authorities in urbanized areas with high intensity fixed guideway systems and/or high intensity motorbus systems operating for at least seven years. Projects are funded at 80 percent federal with a 20 percent local match requirement by statute. FTA will apportion funds to designated recipients. The designated recipients will then allocate funds as appropriate to recipients that are public entities in the urbanized areas. FTA can make grants to direct recipients after sub-allocation of funds. Recipients apply for grants electronically, and FTA collects milestone and financial status reports from designated recipients on a quarterly basis. The information submitted ensures FTA's compliance with applicable federal laws.

DATES: Comments must be submitted before July 8, 2016.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Web site: www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site. (Note: The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *www.regulations.gov.* Commenters should follow the directions below for mailed and hand-delivered comments.
2. *Fax:* 202–493–2251.
3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to Internet users, without change, to *www.regulations.gov.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *www.regulations.gov.* Docket: For access to the docket to read background documents and comments received, go to *www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Eric Hu, Office of Program Management (202) 366–0870, or email: *Eric.Hu@dot.gov.*

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Respondents: State and local governments.

Estimated Annual Burden on Respondents: 58 hours per submission.

Estimated Total Annual Burden: 9,120 hours.

Frequency: Annual.

William Hyre,

Deputy Associate Administrator for Administration.

[FR Doc. 2016–10837 Filed 5–6–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. 2016–0022]

Notice of Request for the Extension of a Currently Approved Information Collection

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to renew the following information collection:

49 U.S.C. Section 5339 Bus and Bus Facilities Program OMB Control No.: 2132–0576

49 U.S.C. Section 5339—Bus and Bus Facilities Formula Program, was originally authorized by the Moving Ahead for Progress in the 21st Century (MAP–21). The program was reauthorized under the Fixing America's Surface Transportation (FAST) Act Section 3017. This program authorizes the Secretary of Transportation to provide funding to replace, rehabilitate and purchase buses and related equipment and to construct bus-related facilities including technological changes or innovations to modify low or no emission vehicles or facilities.

Funding is provided through formula allocations and competitive grants. Two competitive grant programs were added: 5339(b) for bus and bus facility projects and 5339(c) for bus and bus facility projects that support low and zero-emission vehicles. Eligible recipients include 5307 Direct Recipients, States and Federally Recognized Tribes. Eligible sub-recipients include those recipients that receive a grant under the formula or discretionary programs and may allocate amounts from the grant to sub-recipients that are public agencies or private nonprofit organizations engaged in public transportation.

Recipients apply for grants electronically and FTA collects milestone and financial status reports from designated recipients and states on a quarterly basis. The information submitted ensures FTA's compliance with applicable federal laws.

DATES: Comments must be submitted before July 8, 2016.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Web site: www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site. (Note: The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *www.regulations.gov.* Commenters should follow the directions below for mailed and hand-delivered comments.
2. *Fax:* 202–493–2251.
3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to Internet users, without change, to *www.regulations.gov.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *www.regulations.gov.* Docket: For access to the docket to read background documents and comments received, go to *www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Samuel Snead, Office of Program Management (202) 366–1089, or email: *samuel.snead@dot.gov* (Bus Program) or Tara Clark, Office of Program Management (202)366–2623 or email: *tara.clark@dot.gov.*

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Respondents: 5307 Direct Recipients, States and Federally Recognized Indian Tribes.

Estimated Annual Burden on Respondents: 58 hours per submission.

Estimated Total Annual Burden: 9,020 hours.

Frequency: Annual.

William Hyre,

Deputy Associate Administrator for Administration.

[FR Doc. 2016–10838 Filed 5–6–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Increase in Maximum Tuition and Fee Amounts Payable Under the Post-9/11 GI Bill

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the increase in the Post-9/11 GI Bill maximum tuition and fee amounts payable and the increase in the amount used to determine an individual's entitlement charge for reimbursement of a licensing, certification, or national test for the 2016–2017 academic year (August 1, 2016–July 31, 2017).

FOR FURTHER INFORMATION CONTACT: Schnell Carraway, Management and Program Analyst, Education Service (225C), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, Telephone: (202) 461–9800. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: For the 2015–2016 academic year (August 1, 2015–July 31, 2016), the Post-9/11 GI Bill allowed VA to pay the actual net cost of tuition and fees not to exceed the in-state amounts for students pursuing training at public schools: $21,084.89 for students training at private and foreign schools, $12,048.50 for students training at vocational flight schools, and $10,241.22 for students training at correspondence schools. Additionally, the entitlement charge for individuals receiving reimbursement of costs to take a licensing, certification, or national test was one month (rounded to the nearest whole month) for each $1,759.08 received.

Sections 3313, 3315, and 3315A of title 38, United States Code (U.S.C.), direct VA to increase the maximum tuition and fee payments and entitlement-charge amounts each academic year (begins August 1st) based on the most recent percentage increase determined under 38 U.S.C. 3015(h). The percentage increase determined under 38 U.S.C. 3015(h) is effective October 1st of each year. The most recent percentage increase determined under 38 U.S.C. 3015(h) was a 4.2-percent increase, which was effective October 1, 2015.

The maximum tuition and fee payments and entitlement-charge amounts for training pursued under the Post-9/11 GI Bill beginning after July 31, 2016, and before August 1, 2017, are listed below. VA's calculations for the 2016–2017 academic year are based on the 4.2-percent increase.

2016–2017 ACADEMIC YEAR

Type of school	Actual net cost of tuition and fees not to exceed
Post-9/11 GI Bill Maximum Tuition and Fee Amounts	
Public	In-State/Resident Charges.
Private/Foreign	$21,970.46.
Vocational Flight	$12,554.54.
Correspondence	$10,671.35.
Post-9/11 Entitlement Charge Amount for Tests	
Licensing and Certification Tests National Tests	VA will charge one month entitlement (rounded to the nearest whole, non-zero, month) for each $1,832.96 received.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert D. Snyder, Chief of Staff, Department of Veterans Affairs, approved this document on April 11, 2016, for publication.

Dated: May 3, 2016.

Michael Shores,

Chief Impact Analyst, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2016–10744 Filed 5–6–16; 8:45 am]

BILLING CODE 8320–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Monday,
No. 89 May 9, 2016

Book 2 of 2 Books

Pages 28161–28686

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 495

Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 495

[CMS–5517–P]

RIN 0938–AS69

Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repeals the Medicare sustainable growth rate (SGR) methodology for updates to the physician fee schedule (PFS) and replaces it with a new Merit-based Incentive Payment System (MIPS) for MIPS eligible clinicians or groups under the PFS. This proposed rule would establish the MIPS, a new program for certain Medicare-enrolled practitioners. MIPS would consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs), and would continue the focus on quality, resource use, and use of certified EHR technology (CEHRT) in a cohesive program that avoids redundancies. This proposed rule also would establish incentives for participation in certain alternative payment models (APMs) and includes proposed criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations on physician-focused payment models. In this proposed rule we have rebranded key terminology based on feedback from stakeholders, with the goal of selecting terms that would be more easily identified and understood by our stakeholders.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 27, 2016.

ADDRESSES: In commenting, please refer to file code CMS–5517–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5517–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5517–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW.,
Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786 7195 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Molly MacHarris, (410) 786–4461, for inquiries related to MIPS.

James P. Sharp, (410) 786–7388, for inquiries related to APMs.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ABC™	Achievable Benchmark of Care
ACA	The Patient Protection and Affordable Care Act
ACO	Accountable Care Organization
APM	Alternative Payment Model
BPCI	Bundled Payments for Care Improvement
CAH	Critical Access Hospital
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CEHRT	Certified EHR technology
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CJR	Comprehensive Care for Joint Replacement
CMMI	Center for Medicare & Medicaid Innovation (Innovation Center)
CPIA	Clinical Practice Improvement Activity
CPR	Customary, Prevailing, and Reasonable
CPS	Composite Performance Score
CPT	Current Procedural Terminology
CQM	Clinical Quality Measure
EHR	Electronic heath record
EP	Eligible professional
FFS	Fee-for-Service
FQHC	Federally Qualified Health Center
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health
HPSA	Health Professional Shortage Area
HHS	Department of Health & Human Services
HRSA	Health Resources and Services Administration
IT	Information technology

MACRA Medicare Access and CHIP Reauthorization Act of 2015
MEI Medicare Economic Index
MIPAA Medicare Improvements for Patients and Providers Act of 2008
MIPS Merit-Based Incentive Payment System
MLR Minimum Loss Rate
MSPB Medicare Spending per Beneficiary
MSR Minimum Savings Rate
MUA Medically Underserved Area
NPI National Provider Identifier
OCM Oncology Care Model
ONC Office of the National Coordinator for Health Information Technology
PECOS Medicare Provider Enrollment, Chain, and Ownership System
PFPMs Physician Focused Payment Models
PFS Physician Fee Schedule
PHS Public Health Service
PQRS Physician Quality Reporting System
QCDRs Qualified Clinical Data Registries
QP Qualifying APM Professional
QRDA Quality Reporting Document Architecture
QRUR Quality and Resource Use Reports
RBRVS Resource-Based Relative Value Scale
RHC Rural Health Clinic
RVU Relative Value Unit
SGR Sustainable Growth Rate
TCPI Transforming Clinical Practice Initiative
TIN Tax Identification Number
VM Value-based Payment Modifier
VPS Volume Performance Standard

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Executive Summary

1. Purpose

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), amended title XVIII of the Social Security Act (the Act) to repeal the Medicare sustainable growth rate and strengthen Medicare access by improving physician payments and making other improvements, to reauthorize the Children's Health Insurance Program (CHIP), and for other purposes. This rule is needed to propose policies to improve physician payments by changing the way Medicare incorporates quality measurement into payments and by developing new policies to address and incentivize participation in alternative payment models.

This proposed rule would establish the Merit-Based Incentive Payment System (MIPS), a new program for certain Medicare-participating practitioners. MIPS would consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals (EPs), and would continue the focus on quality, resource use, and use of certified EHR technology in a cohesive program that avoids redundancies. This proposed rule also would establish incentives for participation in certain alternative payment models (APMs), supporting the Administration's goals of moving more fee-for-service payments into APMs that focus on better care, smarter spending, and healthier people. This proposed rule also includes proposed criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations to the Secretary on physician-focused payment models (PFPMs).

In this proposed rule we have rebranded key terminology based on feedback from stakeholders, with the goal of selecting terms that would be more easily identified and understood by our stakeholders. We discuss these terminology changes in greater detail in the following sections of this proposed rule.

2. Summary of the Major Provisions

This proposed rule would sunset payment adjustments under the current PQRS, VM, and the Medicare EHR Incentive Program for EPs. Components of these three programs would be carried forward into the new MIPS program.

This proposed rule would establish a new subpart O of our regulations at 42 CFR 414.1300 to implement the new MIPS program as required by the MACRA.

(a) MIPS

In establishing MIPS, this rule would define MIPS program participants as "MIPS eligible clinicians" rather than "MIPS EPs" as that term is defined at section 1848(q)(1)(C) and used throughout section 1848(q) of the Act. MIPS eligible clinicians will include physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and groups that include such clinicians. The rule proposes definitions and requirements for groups. In addition to proposing definitions for MIPS eligible clinicians, the rule also proposes rules for the specific Medicare-enrolled practitioners that would be excluded from MIPS, including newly Medicare-enrolled eligible clinicians, Qualifying APM Participants (QPs), certain Partial Qualifying APM Participants (Partial QPs), and clinicians that fall under the proposed low-volume threshold.

This rule proposes MIPS performance standards and a MIPS performance period of 1 calendar year (January 1 through December 31) for all measures and activities applicable to the four performance categories. Further, we propose to use 2017 as the performance period for the 2019 payment adjustment. Therefore, the first performance period would start in 2017 for payments adjusted in 2019. This time frame is needed to allow data and claims to be submitted and data analysis to occur. In addition, it would allow for a full year of measurement and sufficient time to base adjustments on complete and accurate information.

As directed by the MACRA, this rule proposes measures, activities, reporting, and data submission standards across four performance categories: Quality, resource use, clinical practice improvement activities (CPIAs), and meaningful use of certified EHR technology (referred to in this proposed rule as "advancing care information"). Measures and activities would vary by category and include outcome measures, performance measures, and global and population-based measures. Consideration would be given to the application of measures to non-patient facing MIPS eligible clinicians.

Quality measures would be selected annually through a call for quality measures process. Selection of these measures is proposed to be based on certain criteria that align with CMS priorities, and a final list of quality measures will be published in the **Federal Register** by November 1 of each year. Under the standards proposed in this rule, there would be options for reporting as an individual MIPS eligible clinician or as part of a group. Some data could be submitted via relevant third party data submission entities, such as qualified clinical data registries (QCDRs), health IT vendors,[1] qualified registries, and CMS-approved survey vendors.

Within each performance category, we propose some specific standards, including:

- Quality: For most MIPS eligible clinicians, we propose to include a minimum of six measures with at least one cross-cutting measure (for patient-facing MIPS eligible clinicians) and an outcome measure if available; if an outcome measure is not available, then the eligible clinician would report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. MIPS eligible clinicians can meet this criterion by selecting measures either individually or from a specialty-specific measure set.
- Resource Use: Continuation of two measures from the VM: Total per costs capita for all attributed beneficiaries and Medicare Spending per Beneficiaries (MSPB) with minor technical adjustments. In addition, episode-based measures, as applicable to the MIPS eligible clinician.
- CPIA: We generally encourage but are not requiring a minimum number of CPIAs.
- Advancing Care Information: Assessment based on advancing care information measures and objectives.

We propose standards for measures, scoring, and reporting for MIPS eligible clinicians across all four performance categories outlined in this section. We propose that MIPS eligible clinicians who participate in certain types of APMs will be scored using an APM scoring standard instead of the generally applicable MIPS scoring standard.

The U.S. Department of Health & Human Services' (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting studies and making recommendations on the issue of risk adjustment for socioeconomic status on quality measures and resource use as required by section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) and expects to issue a report to Congress by October 2016. We will closely examine the recommendations issued by ASPE and incorporate them, as feasible and appropriate, in future rulemaking.

We are proposing MIPS eligible clinicians have the flexibility to submit information individually or via a group or an APM Entity group; however, the MIPS eligible clinician would use the same identifier for all performance categories. The proposed scoring methodology has a unified approach across all performance categories, would allow MIPS eligible clinicians to know in advance what they need to do to perform well in MIPS, and eliminates the need for an "all or nothing" scoring as has been the case under some other CMS programs. The four performance category scores (quality, resource use, CPIA, and advancing care information) would be aggregated into a MIPS composite performance score (CPS). The MIPS CPS would be compared against a MIPS performance threshold. The CPS would be used to determine whether a MIPS eligible clinician receives an upward payment adjustment, no payment adjustment, or a downward payment adjustment as appropriate. Payment adjustments would be scaled for budget neutrality, as required by statute. The CPS would also be used to determine whether a MIPS eligible clinician qualifies for an additional positive adjustment factor for exceptional performance.

To ensure that MIPS results are useful and accurate, we propose a process for providing performance feedback to MIPS eligible clinicians. Beginning July 1, 2017, we propose to include information on the quality and resource use performance categories in the performance feedback. Initially, we propose to provide performance feedback on an annual basis. In future years, we may consider providing performance feedback on a more frequent basis as well as adding feedback on the performance categories of CPIA and advancing care information. We propose to make performance feedback available using a CMS designated system. Further, we propose to leverage additional mechanisms such as health IT vendors, registries, and QCDRs to help disseminate data/information contained in the performance feedback to eligible clinicians where applicable.

We propose to adopt a targeted review process under MIPS wherein a MIPS eligible clinician may request that we review the calculation of the MIPS adjustment factor and, as applicable, the calculation of the additional MIPS adjustment factor applicable to such MIPS eligible clinician for a year. We further propose a general process by which a MIPS eligible clinician could request targeted review.

We propose requirements for third-party data submission to MIPS. Specifically, qualified registries, QCDRs, health IT vendors, and CMS-approved survey vendors would have the ability to act as intermediaries on behalf of MIPS eligible clinicians and groups for submission of data to us across the quality, CPIA, and advancing care information performance categories.

We also propose a process for public reporting of MIPS information through the Physician Compare Web site. We propose public reporting of a MIPS eligible clinician's data; in that for each program year, we will post on a public Web site (for example, Physician Compare), in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under the MIPS.

(b) APMs

In this rule, we propose standards we would use for the purposes of the Alternative Payment Model (APM) incentive. The MACRA defines APM for the purposes of the incentive as a model under section 1115A of the Social Security Act (the Act) (excluding a health care innovation award), the Shared Savings Program under section 1899 of the Act, a demonstration under section 1866C of the Act, or a demonstration required by federal law. We propose to define the term "Other Payer APMs" to refer to arrangements in which eligible clinicians may participate through other payers. We also propose to define the term APM Entity as an entity that participates in an APM through a contract with a payer.

APMs that meet the criteria to be Advanced APMs provide the pathway through which eligible clinicians can become QPs and earn incentive payments for participation in APMs as specified under the MACRA. This rule proposes two types of Advanced APMs: Advanced APMs and Other Payer Advanced APMs. To be an Advanced APM, an APM must meet three requirements: (1) Require participants to use certified EHR technology; (2) provide payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and (3) be either a Medical Home Model expanded under section 1115A of the Act or bear more than a nominal amount of risk for monetary loses. In this rule, we propose criteria for each of the requirements to be an Advanced APM.

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[1] We note that, for this proposed rule, a health IT vendor that serves as a third party intermediary to collect or submit data on behalf MIPS eligible clinicians may or may not also be a "health IT developer." Under the ONC Health IT Certification Program (Program), a health IT developer constitutes a vendor, self-developer, or other entity that presents health IT for certification or has health IT certified under the Program. The use of "health IT developer" is consistent with the use of the term "health IT" in place of "EHR" or "EHR technology" under the Program (see 80 FR 62604; and the advancing care information performance category in this rule). Throughout this proposed rule, we use the term "health IT vendor" to refer to entities that support the health IT requirements of a clinician participating in the proposed Quality Payment Program.

To be an Other Payer Advanced APM, a commercial or Medicaid APM must meet three requirements similar to the CMS Advanced APM requirements: (1) Require participants to use certified EHR technology; (2) provide payment based on quality measures comparable to those used in the quality performance category of MIPS; and (3) be either a Medicaid Medical Home Model that is comparable to Medical Home Models expanded under section 1115A of the Act or bear more than a nominal amount of risk for monetary loses.

We propose that we would notify the public of which APMs will be Advanced APMs prior to each QP Performance Period, starting no later than January 1, 2017. This information will be posted on our Web site.

We propose that professional services furnished at Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) that meet certain criteria be counted towards the QP determination.

The MACRA sets a Medicare threshold for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, is applicable beginning with CY 2019. The All-Payer Combination Option, based on the Medicare Option, as well as an eligible clinician's participation in Other Payer Advanced APMs, is applicable beginning with CY 2021. For eligible clinicians to become QPs through the All-Payer Combination Option, an Advanced APM Entity or eligible clinician must submit information to us so that we can determine whether an Other Payer APM is an Other Payer Advanced APM and whether an eligible clinician meets the requisite QP threshold of participation. We propose a methodology and criteria to evaluate eligible clinicians using the All-Payer Combination Option. For purposes of evaluating Other Payer APMs, we also propose criteria for the definition of Medicaid Medical Homes and Medical Home Model.

We propose to identify individual eligible clinicians by a unique APM participant identifier using the individuals' TIN/NPI combinations, and to assess as an APM Entity group all individual eligible clinicians listed as participating in an Advanced APM Entity to determine QP status for a year. We also propose that if an individual eligible clinician who participates in multiple Advanced APM Entities does not achieve QP status through participation in any single APM Entity, we would assess the eligible clinician individually to determine QP status based on combined participation in Advanced APMs.

We propose the method that CMS would use to calculate and disburse the APM Incentive Payments to QPs. We propose specific rules for calculating the APM Incentive Payment when a QP also receives non-fee-for-service payments or payment adjustments through the Medicare EHR Incentive Program, PQRS, VM, MIPS, or other payment adjustment programs.

We propose a process for eligible clinicians to choose whether or not to be subject to the MIPS payment adjustment in the event that they are determined to be Partial QPs.

We propose that we would perform monitoring and compliance around APM Incentive Payments.

We propose a definition for Physician-Focused Payment Models (PFPMs), criteria that would be used by the PFPM Technical Advisory Committee (PTAC), the Secretary, and CMS to evaluate proposals for PFPMs, and the process by which PFPMs would be considered for testing and implementation by CMS after review by the PTAC.

We propose to require MIPS eligible clinicians, as well as EPs, eligible hospitals, and Critical Access Hospitals (CAHs) under the existing EHR Incentive Programs to make a demonstration related to the provisions concerning blocking the sharing of information under section 106(b)(2) of the MACRA and, separately, to demonstrate cooperation with authorized ONC surveillance of certified EHR technology.

3. Summary of Costs & Benefits

Under the MACRA's requirements, MIPS would distribute payment adjustments to between approximately 687,000 and 746,000 eligible clinicians in 2019. Payment adjustments would be based on MIPS eligible clinicians' performance on specified measures and activities within the four performance categories. We estimate that MIPS payment adjustments would be approximately equally distributed between negative adjustments ($833 million) and positive adjustments ($833 million) to MIPS eligible clinicians, to ensure budget neutrality. Additionally, MIPS would distribute approximately $500 million in exceptional performance payments to MIPS eligible clinicians whose performance exceeds a specified threshold. These payment adjustments are expected to drive quality improvement in the provision of MIPS eligible clinicians' care to Medicare beneficiaries and to all patients in the health care system. However, the distribution could change based on the final population of MIPS eligible clinicians for CY 2019 and the distribution of scores under the program.

We estimate that between approximately 30,658 and 90,000 eligible clinicians would become QPs through participation in Advanced APMs, and are estimated to receive between $146 million and $429 million in APM Incentive Payments for CY 2019. As with MIPS, we expect that APM participation would drive quality improvement for clinical care provided to Medicare beneficiaries and to all patients in the health care system.

I. Background

In January 2015, the Administration announced new goals for transforming Medicare by moving away from traditional fee-for-service payments in Medicare towards a payment system focused on linking physician reimbursements to quality care through APMs (*http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html#*) and other value-based purchasing arrangements. This is part of an overarching Administration strategy to transform how health care is delivered in America, changing payment structures to improve quality and patient outcomes.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) of 2015 (Pub. L. 114–10, enacted April 16, 2015, and hereafter referred to as the MACRA), landmark bipartisan legislation, advances a forward-looking, coordinated framework for health care providers to successfully take part in the CMS Quality Payment Program that rewards value and outcomes in one of two ways:

- Merit-Based Incentive Payment System (MIPS).
- Advanced Alternative Payment Models (Advanced APMs).

The MACRA marks a milestone in efforts to improve and reform the health care system. Building off of the successful coverage expansions and improvements to access under the Affordable Care Act, the MACRA puts an increased focus on the quality and value of care delivered. By incentivizing participation in certain APMs, such as Accountable Care Organizations (ACOs), Medical Home Models, and episode payment models, and by incentivizing quality and value for eligible clinicians under the MIPS, we support the nation's progress toward achieving a patient-centered health care system that delivers better care, smarter spending, and healthier people and communities.

The Department is focused on three core strategies to drive continued progress and improvement, and MACRA provides new tools to that end, which build upon existing efforts, such as the CMS Quality Strategy[2]. First, we are focused on improving the way clinicians are paid to incentivize quality and value of care over simply quantity of services. The Quality Payment Program replaces the SGR update formula with Medicare PFS updates ultimately linked to participation in Advanced APMs and also creates a new, sustainable mechanism for calculating payment adjustments for clinicians' services that links payments to quality and value: The Merit-based Incentive Payment System (MIPS), with the ultimate goal of paying for value and better care. By rewarding eligible clinicians based on their performance, MIPS consolidates key components of the PQRS, the VM and the Medicare EHR Incentive Program for EPs into one single, streamlined program based on performance in the following:

- Quality.
- Resource use.
- CPIA.
- Advancing care information.

Second, we are focused on improving the way care is delivered by providing clinical practice support, data and feedback reports to guide improvement and better decision-making. Allowing for stronger, real-time, easy-to-understand feedback and actionable data on eligible clinician performance on clinical quality measures (CQMs), utilization of resources and cost can lead to stronger care coordination, help facilitate and enhance team-based approaches, and support greater integration within practices, improved patient communication, a stronger focus on population health, and continuous learning and rapid-cycle improvement.

Third, we are focused on making data more available and enabling the use of certified EHR technology to support care delivery. Consistent use of certified EHR technology and clinical quality measurement in managing patient populations would help lead to substantial improvements in our health care system, by allowing clinicians to track and take care of their patients throughout the care continuum and to easily and securely access electronic health information to support care when and where it is needed.

By driving significant changes in how care is delivered and changes in the health care system to make it more responsive to patients and families, we believe the Quality Payment Programs would encourage eligible clinicians to be accountable for the health of their patient population and support interested eligible clinicians in their successful transition into APMs. To implement this vision, we propose a program that allows for stronger alignment across requirements while minimizing burden on eligible clinicians. Further, we propose a program that is meaningful, understandable and flexible with a critical focus on transparency, effective communication with stakeholders and operational feasibility. To aid in this process, we have sought feedback from the health care community through various public avenues and will seek comment through this proposed rule. As we establish policies for effective implementation of the MACRA, we are also focused on improving the health system by ensuring that our policies can scale in future years. As we drive change through this proposed rule, we will begin by laying the groundwork for expansion towards an innovative, outcome-focused, patient-centered, resource-effective health system. Through a staged approach we can develop our policies are operationally feasible and made in consideration of system capabilities and of our core strategies to drive progress and reform efforts.

A. Physician and Practitioner Payment Under Medicare

1. History

Medicare payment systems have undergone significant changes since the Act established the Medicare program in 1965. Originally, Medicare was modeled on the existing health insurance marketplace (See 1965 Medicare Amendment to SSA, Pub. L. 89–97). Medicare payments to physicians and hospitals were based on the amounts that had been historically charged by physicians and hospitals for various health care services. Medicare initially paid for physicians' services using a "customary, prevailing, and reasonable" charge (CPR) payment system. (1965 Medicare Amendment to SSA, Pub. L. 89–97). Congress later changed the CPR system in part to counter increased charges to physicians, leading to rapid increases in program payments.

In 1984, Medicare changed the way it paid hospitals to a prospective payment system (Social Security Amendments of 1983, Pub. L. 98–21) that moved away from a charge-based per diem rate and introduced the Medicare Economic Index (MEI) to modify physician payment. The MEI was used to measure the annual increase in practice costs for updating payment for physicians' services.

Beginning in 1992 following the passage of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239, enacted on December 19, 1989), the historical charge-based fee schedule was replaced with a fee schedule that used a Resource-Based Relative Value Scale, developed at Harvard University, which attempted to assess for each service the relative value of a physician's work effort, as well as the practice expenses and malpractice liability expenses involved.

Under OBRA 89, the resource-based Medicare PFS aimed to establish a rational basis for valuing payments for physicians' services. Therefore, under the current resource-based approach, payment for a service depends on the value of the resources involved in performing a particular service.

Following the implementation of the resource-based PFS over several years, the fee schedule has specified Medicare payments for physicians' services. Each medical, surgical and diagnostic service, described by a current procedural terminology (CPT) code is assigned relative value units (RVUs) for three resource categories: Work, practice expense, and malpractice expense. These three RVU values are summed, geographically adjusted, and multiplied by a fixed-dollar conversion factor for the payment year to determine the payment amount for each service or procedure. Over time, we have reviewed and revised the RVU values using our own methodologies and other information.

After the adoption of the resource-based PFS, further amendments to the Act have led to the imposition of spending targets for physicians' services. Initially, the spending limit was set by a Volume Performance Standard (VPS) that tied the annual update to a target that was based on historical trends in physician costs. Because of the way the adjustment was calculated, it produced very unstable updates, with swings that were much greater than the changes in the underlying MEI.

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[2] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997) replaced the VPS with the SGR formula to update the PFS each year. Under BBA, the SGR made several changes including a much more aggressive measure to control spending, tying the allowable increases in physician spending to the growth rate in real GDP per capita. In general, under the SGR formula, if cumulative expenditures from the current period going back to 1996 (the base year) were less than the cumulative spending target over that same period, the annual update was increased according to a statutory formula. However, if spending exceeded the cumulative spending target over the same period, the SGR methodology requires reductions in the fee schedule update to bring spending back in line with the targeted growth rate.

In the initial years of implementation, actual expenditures did not exceed allowed targets. But beginning in 2002, cumulative actual expenditures began to exceed allowed targets for the year, resulting in SGR-mandated reductions in the fee schedule update adjustment factor. The Congress enacted a series of laws to override these reductions. The SGR-based update adjustment factor had not been allowed to take effect since 2003 due to consistent intervention by the Congress to avert payment reductions.

Currently, payments under the Medicare PFS include several payment adjustments that increase or decrease payments to practitioners based on performance. The Tax Relief and Health Care Act of 2006 required the establishment of the PQRS that would include an incentive payment to EPs who satisfactorily report data on quality measures. The Medicare Improvements for Patients and Provider Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008) made the PQRS program permanent. The HITECH Act of 2009, part of the American Recovery and Reinvestment Act (ARRA), established incentive payments to EPs to promote the adoption and meaningful use of certified EHR technology. HITECH provided the statutory basis for the Medicare incentive payments made to meaningful EHR users and also established downward payment adjustments, under Medicare, beginning with calendar year 2015, for EPs that are not meaningful users of certified EHR technology for certain associated reporting periods.

The Affordable Care Act (Pub. L. 111–148) required the establishment of a value-based payment modifier that provides for differential payment to a physician or group of physicians under the Medicare PFS based upon the quality of care furnished compared to cost, that is implemented in a budget-neutral manner. Beginning in 2015, the VM applies to payments for items and services furnished by physicians in groups of 100 or more, and will apply to all physicians and certain types of non-physician practitioners in later years. The VM is being phased in and will apply to all physicians in groups and individual physicians in 2017.

2. Payment Models and Innovation

The policies proposed in this rule are intended to continue to move Medicare away from a primarily volume based fee-for-service (FFS) payment system for physicians and other professionals. As described in this section of the proposed rule, for many years Medicare was primarily a FFS payment system that paid health care providers based on the volume of services they delivered, rather than the value of those services. This contributed to increased costs without incentivizing improvement in the quality of care. Over time, the Congress and CMS have taken progressive steps to move toward paying for value, as demonstrated by Medicare's long history of testing alternative payment methods.

Medicare has been testing alternative payment methods since waiver authority for Medicare demonstrations was granted through section 402 of the Social Security Amendments of 1967. Demonstrations and pilot programs, (also called "research studies") are special projects that test improvements in Medicare coverage, payment, and quality of care (*https://www.medicare.gov/sign-up-change-plans/medicare-health-plans/other-health-plans/other-medicare-health-plans.html*). Demonstrations have examined whether alternative payment methods increase the efficiency of Medicare and Medicaid and whether payment for services not otherwise covered increases the effectiveness of care. Medicare's demonstration authority has allowed it to test the effect of policy changes on Medicare on a small scale in order to inform broader policy.

The Affordable Care Act includes a number of provisions, for example, the Medicare Shared Savings Program, designed to improve the quality of Medicare services, support innovation and the establishment of new payment models, better align Medicare payments with health care provider costs, strengthen Medicare program integrity, and put Medicare on a firmer financial footing.

The Affordable Care Act created the Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center was established by section 1115A of the Act (as added by section 3021 of the Affordable Care Act). The Innovation Center's mandate gives it flexibility within the parameters of section 1115A of the Act to select and test promising innovative payment and service delivery models. Congress created the Innovation Center for the purpose of testing innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care provided to those individuals who receive Medicare, Medicaid, or CHIP benefits. *See https://innovation.cms.gov/about/index.html.* Models that have met those expectations may be expanded in scope through rulemaking up to a national scale.

To better coordinate these models and demonstration projects and to avoid duplicative efforts and expenses, the former Office of Research, Development and Information, which oversaw statutory demonstrations and those under section 402 etc., was merged with the Innovation Center in early 2011. As a result, the Innovation Center oversees not only initiatives that are authorized under section 1115A of the Act, but also activities under several other authorities, including other provisions of the Affordable Care Act, and other laws and projects authorized by section 402 of the Social Security Amendments of 1967, as amended.

The Innovation Center's portfolio of models has attracted participation from a broad array of health care providers, states, payers, and other stakeholders, and serves Medicare, Medicaid, and CHIP beneficiaries in all 50 states, the District of Columbia, and Puerto Rico. We estimate that over 4.7 million Medicare, Medicaid, and CHIP beneficiaries are or soon will be receiving care furnished by the more than 61,000 eligible clinicians participating in APMs tested by the CMS Innovation Center.

Beyond the care improvements for these beneficiaries, Innovation Center models are affecting millions of additional Americans by engaging thousands of other health care providers, payers, and states in model tests and through quality improvement efforts across the country. Many payers other than CMS have implemented alternative payment arrangements or models, or have collaborated in

Innovation Center models. The participation of multiple payers in alternative delivery and payment models increases momentum for delivery system transformation and encourages efficiency for health care organizations.

The Innovation Center works directly with other CMS components and colleagues throughout the federal government in developing and testing new payment and service delivery models. Other federal agencies with which the Innovation Center has collaborated include the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Agency for Healthcare Research and Quality (AHRQ), Office of the National Coordinator for Health Information Technology (ONC), Administration for Community Living (ACL), Department of Housing and Urban Development (HUD), Administration for Children and Families (ACF), and the Substance Abuse and Mental Health Services Administration (SAMHSA). These collaborations help the Innovation Center effectively test new models and execute mandated demonstrations.

B. Current Reporting Programs and Regulations (Overview)

The MACRA's passage has led to several changes with the existing Medicare PFS, various Medicare payment programs that tie payment to value, and the testing of alternative payment models. Specifically, the MACRA's enactment consolidated aspects of certain quality reporting and performance programs into the new MIPS, including the meaningful use of certified EHR technology (section 1848(o) of the Act), the PQRS (section 1848(k) and (m) of the Act, and the VM (section 1848(p) of the Act). The following section provides an overview of existing programs and the extent of their programs before and after the MACRA.

Currently, the Medicare EHR Incentive Program has been divided into three progressive stages of meaningful use with certain specified requirements that EPs must meet in order to qualify for Medicare EHR incentive payments and avoid downward payment adjustments. Full achievement of these requirements designated an EP as a "meaningful EHR user" and made that EP eligible for incentive payments and not subject to downward payment adjustments. The MACRA's enactment altered the EHR Incentive Programs such that the existing Medicare payment adjustment for an EP under 1848(a)(7)(A) of the Act ends after CY 2018. Using certified EHR technology is included in MIPS as part of the advancing care information component of the overall performance score. Generally, the MACRA did not change hospital participation in the Medicare EHR Incentive Program or participation for EPs in the Medicaid EHR Incentive Program.

PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides for incentive payments (which ended in 2014) and payment adjustments (which began in 2015) to EPs and group practices based on whether they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period or to EPs and group practices based on whether they satisfactorily participate in a qualified clinical data registry (QCDR). The MACRA ends the PQRS adjustment after CY 2018 and provides for the inclusion of various aspects of PQRS in MIPS as part of the quality component of the overall performance score.

Section 1848(p) of the Act, as amended by the Affordable Care Act, required that we establish a VM that provides for differential payment under the Medicare PFS based upon the quality of care furnished compared to cost and apply it to specific physicians and groups of physicians as determined appropriate by the Secretary starting in 2015 and to all physicians by 2017. In the CY 2013 PFS final rule with comment period (77 FR 69307), we discussed the goals of the VM and also established the specific principles that should govern the implementation of the VM. The MACRA sunsets the VM, ending it after CY 2018 and establishing certain aspects of the VM as part of the resource use component of MIPS in CY 2019.

C. Overview of Section 101 of the MACRA

Section 101 of the MACRA amended sections 1848(d) and (f) of the Act to repeal the SGR formula for updating Medicare PFS payment rates and substituted a series of specified annual update percentages. Section 101 goes on to establish a new methodology that ties annual PFS payment adjustments to value for MIPS eligible clinicians. Section 101 also creates an incentive program to encourage participation by eligible clinicians in Advanced APMs.

Section 1848(q) of the Act, as added by section 101(c) of the MACRA, requires establishment of the MIPS, applicable beginning with payments for items and services furnished on or after January 1, 2019, under which the Secretary is required to: (1) Develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for a performance period for a year; (2) using the methodology, provide a CPS for each MIPS eligible clinician for each performance period; and (3) use the CPS of the MIPS eligible clinician for a performance period for a year to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the MIPS eligible clinician for the year. Under section 1848(q)(2)(A) of the Act, a MIPS eligible clinician's CPS is determined using four performance categories: (1) Quality; (2) resource use; (3) CPIA; and (4) advancing care information. Section 1848(q)(10) of the Act requires the Secretary to consult with stakeholders (through a request for information (RFI) or other appropriate means) in carrying out the MIPS, including for the identification of measures and activities for each of the four performance categories under the MIPS, the methodology to assess each MIPS eligible clinician's total performance to determine their MIPS CPS, the methodology to specify the MIPS adjustment factor for each MIPS eligible clinician for a year, and the use of QCDRs for purposes of the MIPS.

Section 1848(q)(11) of the Act, as added by section 101(c) of the MACRA, provides for technical assistance to MIPS eligible clinicians in small practices, rural areas, and practices located in geographic health professional shortage areas (HPSAs). In general, the section requires the Secretary to enter into contracts or agreements with appropriate entities (such as quality improvement organizations, regional extension centers (as described in section 3012(c) of the Public Health Service (PHS) Act), or regional health collaboratives) (such as those identified in section 1115A of the Act) to offer guidance and assistance to MIPS eligible clinicians in practices of 15 or fewer eligible clinicians. Priority is to be given to such practices located in rural areas which we propose to define at § 414.1305 to include clinicians in counties designated as Micropolitan or Non-Core Based Statistical Areas (CBSAs), using HRSA's 2014–2015 Area Health Resource File (*http://datawarehouse.hrsa.gov/data/datadownload/ahrfdownload.aspx*), HPSAs (as designated under section 332(a)(1)(A) of the PHS Act), medically underserved areas (MUAs), and practices with low composite scores, for the MIPS performance categories or in transitioning to the implementation of, and participation in, an APM. Details regarding the technical assistance program are outside the scope of this proposed rule, and will be addressed in separate guidance.

Section 101(e) of the MACRA encourages participation in APMs by eligible clinicians and other eligible clinicians, and promotes the development of PFPMs by creating the PTAC. Specifically, this section: (1) Creates a payment incentive that applies to eligible clinicians from 2019 through 2024 who are Qualifying APM Participants (QPs) during the respective performance years, and provides for a higher fee schedule update for eligible clinicians who are QPs for a year beginning in 2026; (2) requires the establishment of a process for stakeholders to propose PFPMs to an independent PTAC that will review, comment on, and provide recommendations to the Secretary on the proposed PFPMs; and (3) requires CMS to establish criteria for PFPMs for use by the PTAC in making comments and recommendations to the Secretary. Additionally, section 101(c)(1) of the MACRA exempts QPs from payment adjustments under MIPS.

D. Stakeholder Input

In developing this proposed rule, in accordance with the law, we have sought feedback from stakeholders throughout the process such as in the 2016 Medicare PFS Proposed Rule; the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models (hereafter referred to as the MIPS and APMs RFI); listening sessions; conversations with a wide number of stakeholders; and conversations with tribes and tribal officials through CMS' Tribal Technical Advisory Group. In addition, we note that the National Indian Health Board has requested an opportunity for consultation with CMS, as well as that we coordinate its standards with the Indian Health Service. Through the MIPS and APMs RFI published in the **Federal Register** on October 1, 2015 (80 FR 59102, 59102–59113), the Secretary of Health and Human Services (the Secretary) solicited comments regarding implementation of certain aspects of the MIPS and broadly sought public comments on the topics in section 101 of the MACRA, including the incentive payments for participation in APMs and increasing transparency of PFPMs. We received a high number of public comments in response to the MIPS and APMs RFI from a broad range of sources including professional associations and societies, physician practices, hospitals, patient groups, and health IT vendors.

We appreciate the high level of interest expressed by commenters and acknowledge their valued input throughout this proposed rule, providing summaries of RFI comments in relevant sections of this rule. In general, commenters supported the passage of regulations implementing the MACRA and maintain optimism as we move from fee-for-service Medicare payment towards an enhanced focus on the quality and value of care. Public support for the MACRA focuses on the potential of a value-based program to provide enough flexibility to be applied meaningfully to physician practices and patient quality of care. Commenters cautioned us to avoid elements of prior reporting programs that have been perceived as too focused on the volume of measures reported rather than measure relevance and impact on treatment. Commenters also requested that we avoid implementing additional requirements on top of the fee-for-service system, which would increase the reporting and compliance burden for eligible clinicians. Commenters believe the underlying goal in establishing the MACRA should be to create a new program that combines a limited (yet meaningful) set of requirements with choices for health care providers on how to meet those requirements. Commenters requested that there be broad opportunities to participate in APMs and the development of new Advanced APMs, and that resources be made available to assist them in moving towards participation in APMs if they do not already participate. Commenters expressed eagerness to participate in Advanced APMs and to be a part of transforming care.

Once again, we thank stakeholders for their considered responses through various venues including comments to the MIPS and APMs RFI. We intend to continue open communication with stakeholders (including consultation with tribes and tribal officials) on an ongoing basis, and we look forward to comments on the policies proposed in this rule.

II. Provisions of the Proposed Regulations

A. Establishing MIPS and the APM Incentive

Section 1848(q) of the Act, as added by section 101(c) of the MACRA, requires establishment of the MIPS (see section I.C. of this proposed rule for additional background information). Section 101(e) of the MACRA promotes the development of, and participation in, APMs for eligible clinicians (see section I.C. of this proposed rule for additional background information). Further information will be provided in future rulemaking.

B. Program Principles and Goals

Through the MACRA amendments, we believe the Congress sets broad goals to be accomplished intended to improve care and health outcomes for every American. More specifically, our goal with the Quality Payment Program is to continue to support health care quality, efficiency, and patient safety. MIPS promotes better care, healthier people, and smarter spending by evaluating MIPS eligible clinicians using a CPS that incorporates MIPS eligible clinicians' performance on quality, resource use, clinical practice improvement activities, and advancing care information. Under the incentives for participation in Advanced APMs, our goals, described in greater detail in section II.F. of this proposed rule, are to expand the opportunities for participation in APMs, maximize participation in current and future Advanced APMs, create clear and attainable standards for incentives, promote the continued flexibility in the design of APMs, and support multi-payer initiatives across the health care market. The Quality Payment Program will encourage more MIPS eligible clinicians to participate in Advanced APMs, which link quality and value to payment. The APM Incentive Payment for eligible clinicians who qualify as QPs will only be available through Advanced APMs, but it is a powerful incentive to increase participation in those APMs. MIPS eligible clinicians participating in APMs (who do not qualify as QPs) will receive favorable scoring under certain MIPS categories.

Our strategic goals in developing the Quality Payment Program include: (1) Design a patient-centered approach to program development that leads to better, smarter, and healthier care; (2) develop a program that is meaningful, understandable, and flexible for participating clinicians; (3) design incentives that drive delivery system reform principles and participation in APMs; and (4) ensure close attention to CMS' excellence in implementation, effective communication with stakeholders and operational feasibility.

C. Changes to Existing Programs

1. Sunsetting of Current Payment Adjustment Programs

Section 101(b) of the MACRA calls for the sunsetting of payment adjustments under three existing programs for Medicare enrolled physicians and other practitioners:

- The PQRS that incentivizes EPs to report on quality measures;
- The VM that provides for budget neutral, differential payment adjustment for EPs in physician groups and solo practices based on quality of care compared to cost; and
- The Medicare EHR Incentive Program for EPs that entails meeting certain requirements for the use of certified EHR technology.

Accordingly, we propose to revise certain regulations associated with these programs. We are not proposing to delete these regulations entirely, as the final payment adjustments under these programs will not occur until the end of 2018. For PQRS, we propose to revise § 414.90(e) introductory text and § 414.90(e)(1)(ii) to continue payment adjustments through 2018.

Similarly, we are proposing to amend the regulation text at § 495.102(d) to remove references to the payment adjustment percentage for years after the 2018 payment adjustment year and add a terminal limit of the 2018 payment adjustment year.

We are not proposing changes to 42 CFR part 414 subpart N—Value-Based Payment Modifier Under the PFS (§ 414.1200–1285), at this time. These regulations are already limited to certain years.

We invite comments on these proposed regulatory changes.

2. Meaningful Use Prevention of Information Blocking and Surveillance Demonstrations for MIPS Eligible Clinicians, EPs, Eligible Hospitals, and CAHs

a. Cooperation With Surveillance and Direct Review of Certified EHR Technology

We are proposing to require EPs, eligible hospitals, and CAHs to attest (as part of their demonstration of meaningful use under the Medicare and Medicaid EHR Incentive Programs) that they have cooperated with the surveillance of certified EHR technology under the ONC Health IT Certification Program, as authorized by 45 CFR part 170, subpart E. Similarly, we are proposing to require such an attestation from all eligible clinicians under the advancing care information performance category of MIPS, including eligible clinicians who report on the advancing care information performance category as part of an APM Entity group under the APM Scoring Standard, as discussed in section II.E.5.h of this proposed rule.

On October 16, 2015, ONC published the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule ("2015 Edition final rule"). The final rule made changes to the ONC Health IT Certification Program that strengthen the testing, certification, and surveillance of health IT. In addition, the final rule clarified and expanded the responsibilities of ONC-Authorized Certification Bodies (ONC–ACBs) with respect to the surveillance of certified EHR technology and other health IT certified under the ONC Health IT Certification Program, including requirements for ONC–ACBs to conduct more frequent and more rigorous surveillance of certified technology and capabilities "in the field" (80 FR 62707). The purpose of in-the-field surveillance is to provide greater assurance that health IT meets certification requirements not only in a controlled testing environment but also when used by health care providers in actual production environments (80 FR 62707).

In addition to these changes, on March 2, 2016, ONC published the ONC Health IT Certification Program: Enhanced Oversight and Accountability proposed rule, which would expand ONC's role to strengthen oversight under the ONC Health IT Certification Program by providing a means for ONC to directly review and evaluate the performance of certified health IT in certain circumstances, such as in response to potential systemic or widespread issues, or in response to problems or issues that could pose a risk to public health or safety, compromise the security or privacy of patients' health information, or give rise to other exigencies (81 FR 11055).

These efforts to strengthen surveillance and other oversight of certified health IT, including through expanded in-the-field surveillance and ONC direct review of technology and capabilities, are critical to the success of HHS programs and initiatives that require the use of certified health IT to improve health care quality and the efficient delivery of care. With respect to the use of certified EHR technology under the Medicare and Medicaid EHR Incentive Programs and the MIPS Program, effective surveillance and oversight is fundamental to providing basic confidence that such technology consistently meets applicable standards, implementation specifications, and certification criteria adopted by the Secretary when it is used by eligible clinicians, EPs, eligible hospitals, and CAHs, as well as by other persons with whom eligible clinicians, EPs, eligible hospitals, and CAHs need to exchange electronic health information to comply with program requirements. The need to ensure that technology consistently meets applicable standards, implementation specifications, and certification criteria is important both at the time it is certified and on an ongoing basis when it is implemented and used in the field by eligible clinicians, EPs, eligible hospitals, and CAHs in order to meet objectives and measures under the Medicare and Medicaid EHR Incentive Program or MIPS. Efforts to strengthen surveillance and oversight of certified EHR technology in the field will become even more important as the types and capabilities of certified EHR technology continue to evolve and with the onset of Stage 3 of the Medicare and Medicaid EHR Incentive Programs and MIPS, which include heightened requirements for sharing electronic health information with other providers and with patients using a broad range of certified EHR technology and other health IT.[3] Finally, we note that effective surveillance and oversight of certified EHR technology is necessary if eligible clinicians, EPs, eligible hospitals, and CAHs are to be able to rely on certifications issued under the ONC Health IT Certification Program as the basis for selecting appropriate technologies and capabilities that support the use of certified EHR technology while avoiding potential implementation and performance issues.

For all of these reasons, the effective surveillance and oversight of certified health IT, and certified EHR technology in particular, is necessary to enable eligible clinicians, EPs, eligible hospitals, and CAHs to demonstrate that they are using certified EHR technology in a meaningful manner as required by sections 1848(o)(2)(A)(i) and 1886(n)(3)(A)(i) of the Act. Yet as ONC observed in the 2015 Edition final rule, such surveillance and oversight will not be effective unless EPs, eligible hospitals, and CAHs are actively engaged and cooperate with the authorized surveillance and oversight of their technology, including by granting access to and assisting ONC and ONC–ACBs to observe the performance of production systems (80 FR 62716).

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[3] For example, EPs, eligible hospitals, and CAHs may meet the Stage 3 measure for care coordination (42 CFR 495.24(d)(6)) by providing patients with access to their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT. As another example, EPs, eligible hospitals, and CAHs must satisfy measures for health information exchange (§ 495.24(d)(7)) that require receiving and incorporating health information from other certified EHR technology.

Accordingly, we are proposing that as part of demonstrating that it is using certified EHR technology in a meaningful manner, an eligible clinician, EP, eligible hospital, or CAH must demonstrate its cooperation with these authorized surveillance and oversight activities. We are proposing to revise the definition of a meaningful EHR user at § 495.4, as well as the attestation requirements at § 495.40(a)(2)(i)(H) and § 495.40(b)(2)(i)(H) to require EPs, eligible hospitals, and CAHs to attest their cooperation with certain authorized health IT surveillance and direct review activities, described in more detail in this section of the rule, as part of demonstrating meaningful use under the Medicare and Medicaid EHR Incentive Programs. Similarly, we are proposing to include an identical attestation requirement in the submission requirements for eligible clinicians under the advancing care information performance category proposed at § 414.1375.

We propose that eligible clinicians, EPs, eligible hospitals, and CAHs would be required to attest that they have cooperated in good faith with the surveillance and ONC direct review of their health IT certified under the ONC Health IT Certification Program, as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT. Under the terms of the attestation, such cooperation would include responding in a timely manner and in good faith to requests for information (for example, telephone inquiries, written surveys) about the performance of the certified EHR technology capabilities in use by the provider in the field. The provider's cooperation would also include accommodating requests (from ONC-Authorized Certification Bodies or from ONC) for access to the provider's certified EHR technology (and data stored in such certified EHR technology) as deployed by the provider in its production environment, for the purpose of carrying out authorized surveillance or direct review, and to demonstrate capabilities and other aspects of the technology that are the focus of such efforts, to the extent that doing so would not compromise patient care or be unduly burdensome for the eligible clinician, EP, eligible hospital, or CAH.

We understand that cooperating with in-the-field surveillance may require prioritizing limited time and other resources. We note that ONC has established safeguards to minimize the burden of surveillance on eligible clinicians, EPs, eligible hospitals, and CAHs. In conducting randomized surveillance, ONC–ACBs must use consistent, objective, valid, and reliable methods to select the locations at which the surveillance will be performed (80 FR 62715). ONC–ACBs may also use appropriate sampling methodologies to minimize disruption to any individual provider or class of providers and to maximize the value and impact of surveillance activities for all providers and stakeholders (80 FR 62715). Moreover, if an ONC–ACB makes a good faith effort but is unable to complete in-the-field surveillance at a particular location, it may exclude the location and substitute a different location for surveillance (80 FR 62716).

In addition, we note that ONC has clarified, in consultation with the Office for Civil Rights, that ONC–ACBs engaging in authorized surveillance of certified EHR technology under the ONC Health IT Certification Program meet the definition of a "health oversight agency" in the HIPAA Privacy Rule (45 CFR 164.501), and as such a health care provider is permitted to disclose protected health information (PHI) (without patient authorization and without a business associate agreement) to an ONC–ACB during the limited time and as necessary for the ONC–ACB to perform the required on-site surveillance of the certified EHR technology (45 CFR 164.512(d)(1)(iii)) (80 FR 62716).[4]

For the foregoing reasons, we believe this proposal will support the surveillance and oversight of certified health IT, as necessary to support meaningful use of CEHRT for all eligible clinicians under the MIPS program, as well as EPs, eligible hospitals and CAHs under the Medicare and Medicaid EHR Incentive Programs, while ensuring that such surveillance or review does not create unnecessary or unreasonable burdens for health care providers or patients. We request public comment on this proposal.

b. Support for Health Information Exchange and the Prevention of Information Blocking

To prevent actions that block the exchange of information, section 106(b)(2)(A) of the MACRA amended section 1848(o)(2)(A)(ii) of the Act to require that, to be a meaningful EHR user, an EP must demonstrate that he or she has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology. Section 106(b)(2)(B) of MACRA made corresponding amendments to section 1886(n)(3)(A)(ii) of the Act for eligible hospitals and, by extension, under section 1814(l)(3) of the Act for CAHs. Sections 106(b)(2)(A) and (B) of the MACRA provide that the manner of this demonstration is to be through a process specified by the Secretary, such as the use of an attestation. Section 106(b)(2)(C) of the MACRA states that the demonstration requirements in these amendments shall apply to meaningful EHR users as of the date that is 1 year after the date of enactment, which would be April 16, 2016.

On December 16, 2014, in an explanatory statement accompanying the Consolidated and Further Continuing Appropriations Act,[5] Congress urged ONC to take steps to decertify products that proactively block the sharing of information because those practices frustrate congressional intent, devalue taxpayer investments in certified EHR technology, and make certified EHR technology less valuable and more burdensome for eligible hospitals and eligible health care providers to use.[6] Congress also asked for a detailed report on health information blocking, which ONC delivered on April 10, 2015. In the report, and based on the available evidence and its own experience, ONC found that some persons and entities—including some health care providers—are knowingly and unreasonably interfering with the exchange or use of electronic health information in ways that limit its availability and use to improve health and health care.[7]

Following these activities, on April 16, 2015, the MACRA was enacted, including section 106(b)(2), which amended sections 1848(o)(2)(A)(ii) and 1886(n)(3)(A)(ii) of the Act, as discussed in this section of the rule. Prior to these amendments, to be treated as a meaningful EHR user, an EP, eligible hospital, or CAH had to demonstrate to the satisfaction of the Secretary that its certified EHR technology was connected during the relevant EHR reporting period in a manner that provided, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination. As amended, respectively, by sections 106(b)(2)(A) and (B) of the MACRA, sections 1848(o)(2)(A)(ii) and 1886(n)(3)(A)(ii) of the Act now require that, in addition to demonstrating such connectivity, an eligible clinician, EP, eligible hospital, or CAH must also demonstrate that it did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of the certified EHR technology.

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[4] *See also* ONC Regulation FAQ #45 [12–13–045–1], available at *http://www.healthit.gov/policy-researchers-implementers/45-question-12-13-045.*

[5] Pub. L. 113–235.

[6] 160 Cong. Rec. H9047, H9839 (daily ed. Dec. 11, 2014) (explanatory statement submitted by Rep. Rogers, chairman of the House Committee on Appropriations, regarding the Consolidated and Further Continuing Appropriations Act, 2015).

[7] ONC, *Report to Congress on Health Information Blocking* (April 10, 2015), available at *https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.*

We believe that, at a minimum, such a demonstration would need to provide substantial assurance not only that the certified EHR technology was connected in accordance with applicable standards during the relevant EHR reporting period, but that the eligible clinician, EP, eligible hospital, or CAH acted in good faith to implement and use the certified EHR technology in a manner that supported and did not interfere with the electronic exchange of health information among health care providers and with patients to improve quality and promote care coordination. Accordingly, we are proposing that such a demonstration be made through an attestation comprising three statements related to health information exchange and information blocking, which are set forth in our proposal in this rule. We are proposing to revise the definition of a meaningful EHR user at § 495.4 and the attestation requirements at § 495.40(a)(2)(i)(I) and § 495.40(b)(2)(i)(I) to provide that, for attestations submitted on or after April 16, 2016, an EP, eligible hospital, or CAH under the Medicare and Medicaid EHR Incentive Programs must attest to this three-part attestation. For the same reasons stated in this section of the rule, we are also proposing to require such an attestation from all eligible clinicians under the advancing care information performance category of MIPS, including eligible clinicians who report on the advancing care information performance category as part of an APM Entity group under the APM Scoring Standard, as discussed in section II.E.5.h of this proposed rule. As noted in this section, the attestation we are proposing would consist of three statements related to health information exchange and information blocking. First, the eligible clinician, EP, eligible hospital, or CAH would be required to attest that it did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

Second, the eligible clinician, EP, eligible hospital, or CAH would be required to attest that it implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: connected in accordance with applicable law; compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; implemented in a manner that allowed for timely access by patients to their electronic health information; (including the ability to view, download, and transmit this information) and implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.

Third, the eligible clinician, EP, eligible hospital, or CAH would be required to attest that it responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor. We invite public comment on this proposal, including whether the foregoing statements could provide the Secretary with adequate assurances that an eligible clinician, EP, eligible hospital, or CAH has complied with the statutory requirements for information exchange. We also encourage public comment on whether there are additional facts or circumstances to which eligible clinicians, EPs, eligible hospitals, or CAHs should be required to attest, or whether there is additional information that they should be required to report.

D. Definitions

At § 414.1305, subpart O, we are proposing definitions for the following terms:

- Additional performance threshold.
- Advanced Alternative Payment Model (Advanced APM).
- Advanced APM Entity.
- Affiliated practitioner.
- Alternative Payment Model (APM).
- APM Entity.
- APM Entity group.
- APM Incentive Payment.
- Attestation.
- Attributed beneficiary.
- Attribution-eligible beneficiary.
- Certified Electronic Health Record Technology (CEHRT).
- Clinical Practice Improvement Activity (CPIA).
- CMS-approved survey vendor.
- CMS Web Interface.
- Composite performance score (CPS).
- Covered professional services.
- Eligible clinician.
- Episode payment model.
- Estimated aggregate payment amounts.
- Group.
- Health professional shortage areas (HPSA).
- High priority measure.
- Hospital-based MIPS eligible clinician.
- Incentive payment base period.
- Low-volume threshold.
- Meaningful EHR user for MIPS.
- Measure benchmark.
- Medicaid APM.
- Medical Home Model.
- Medicaid Medical Home Model.
- Merit-Based Incentive Payment System (MIPS).
- MIPS APM.
- MIPS Payment Year.

MIPS eligible clinician.

- MIPS payment year.
- New Medicare-Enrolled MIPS eligible clinician.
- Non-patient-facing MIPS eligible clinician.
- Other Payer Advanced APM.
- Partial Qualifying APM Participant (Partial QP).
- Partial QP patient count threshold.
- Partial QP payment amount threshold.
- Participation List.
- Performance category score.
- Performance standards.
- Performance threshold.
- Qualified Clinical Data Registry (QCDR).
- Qualified registry.
- QP patient count threshold.
- QP payment amount threshold.
- QP Performance Period.
- Qualifying APM Participant (QP).
- Rural areas.
- Small practices.
- Threshold Score.
- Topped out measure.

Some of these terms are new in conjunction with MIPS and APMs, while others are used in existing CMS programs. For the new proposed terms and definitions, we note that some of them have been developed alongside proposed policies of this regulation while others are defined by statute. Specifically, the following terms and definitions were established by the MACRA: APM, CPIA, Eligible Alternative Payment Entity (which we have termed Advanced APM Entity), Eligible professional or EP (which we have termed eligible clinician), MIPS Eligible professional or MIPS EP (which we have termed MIPS eligible clinicians), Qualifying APM Participant, and Partial Qualifying APM Participant.

We invite public comments on all of these proposed terms and definitions, and discuss most of them in detail in relevant sections of this preamble.

E. MIPS Program Details

1. MIPS Eligible Clinicians

We believe a successful MIPS program fully equips clinicians identified as MIPS eligible clinicians with the tools and incentives to focus on improving health care quality, efficiency, and patient safety for all their patients. Under MIPS, MIPS eligible clinicians are incentivized to engage in proven improvement measures and activities that impact patient health and safety and are relevant for their patient population. One of our strategic goals in developing the MIPS program is to advance a program that is meaningful, understandable, and flexible for participating MIPS eligible clinicians. One way we believe this will be accomplished is by minimizing MIPS eligible clinicians' burden. We have made an effort to focus on policies that remove as much administrative burden as possible from MIPS eligible clinicians and their practices while still providing meaningful incentives for high-quality, efficient care. In addition, we hope to balance practice diversity with flexibility to address varied MIPS eligible clinicians' practices. Examples of this flexibility include special consideration for non-patient-facing MIPS eligible clinicians, an exclusion from MIPS for eligible clinicians who do not exceed the low-volume threshold, and other proposals discussed below.

a. Definition of a MIPS Eligible Clinician

Section 1848(q)(1)(C)(i) of the Act, as added by section 101(c)(1) of the MACRA, outlines the general definition of a MIPS eligible clinician for the MIPS program. Specifically, for the first and second year for which MIPS applies to payments (and the performance period for such years) a MIPS eligible clinician is defined as a physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), and a group that includes such professionals. The statute also provides flexibility to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians in the third and subsequent years of MIPS. As discussed in section II.E.3. of this proposed rule, section 1848(q)(1)(C)(ii) and (v) of the Act specifies several exclusions from the definition of a MIPS eligible clinician. In addition, section 1848(q)(1)(A) of the Act requires the Secretary to permit any eligible clinician (as defined in section 1848(k)(3)(B) of the Act) who is not a MIPS eligible clinician the option to volunteer to report on applicable measures and activities under MIPS. Section 1848(q)(1)(C)(vi) of the Act clarifies that a MIPS adjustment factor (or additional MIPS adjustment factor) will not be applied to an individual who is not a MIPS eligible clinician for a year, even if such individual voluntarily reports measures under MIPS.

To implement the MIPS program we must first establish and define a MIPS eligible clinician in accordance with the statutory definition. We propose to define a MIPS eligible clinician at § 414.1305 as a physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), and a group that includes such professionals. In addition, we propose that Qualifying APM Participants, Partial Qualifying APM Participants who do not report data under MIPS, low-volume threshold eligible clinicians, and new Medicare-enrolled eligible clinicians as defined at § 414.1305 would be excluded from this definition per the statutory exclusions defined in section 1848(q)(1)(C)(ii) and (v) of the Act. We intend to consider using our authority under section 1848(q)(1)(C)(i)(II) of the Act to expand the definition of MIPS eligible clinician to include additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) through rulemaking in future years.

In addition, in accordance with section 1848(q)(1)(A) and (q)(1)(C)(vi) of the Act, we propose to allow eligible clinicians who are not MIPS eligible clinicians as defined at proposed § 414.1305 the option to voluntarily report measures and activities for MIPS. We propose at § 414.1310(d) that those eligible clinicians who are not MIPS eligible clinicians, but who voluntarily report on applicable measures and activities specified under MIPS, would not receive an adjustment under MIPS; however, they will have the opportunity to gain experience in the MIPS program. We are particularly interested in public comment regarding the feasibility and advisability of voluntary reporting in the MIPS program for entities such as Rural Health Clinics (RHCs) and/or Federally Qualified Health Centers (FQHCs), including comments regarding the specific technical issues associated with reporting that are unique to these health care providers. We anticipate some eligible clinicians that will not be MIPS eligible clinicians during the first 2 years of MIPS, such as physical and occupational therapists, clinical social workers, and others that have been reporting quality measures under the PQRS for a number of years, will want to have the ability to continue to report and gain experience under MIPS. We request comments on these proposals.

b. Non-Patient-Facing MIPS Eligible Clinicians

Section 1848(q)(2)(C)(iv) of the Act requires the Secretary, in specifying measures and activities for a performance category, to give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient. To the extent feasible and appropriate, the Secretary may take those circumstances into account and apply alternative measures or activities that fulfill the goals of the applicable performance category to such non-patient-facing MIPS eligible clinicians. In carrying out these provisions, we are required to consult with non-patient-facing MIPS eligible clinicians.

In addition, section 1848(q)(5)(F) of the Act allows the Secretary to re-weight MIPS performance categories if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician. We assume many non-patient-facing MIPS eligible clinicians will not have sufficient measures and activities applicable and available to report under the performance categories under MIPS. We refer readers to section II.E.6. of this proposed rule to discuss how we address performance categories weighting for MIPS eligible clinicians for whom no measures exist in a given category.

To establish policies surrounding non-patient-facing MIPS eligible clinicians, we must first define the term "non-patient-facing." Currently, the PQRS, VM, and Medicare EHR Incentive Program include two existing policies for considering whether an EP is providing patient-facing services. To determine, for purposes of PQRS, whether an EP had a "face-to-face" encounter with Medicare patients, we assess whether the EP billed for services under the PFS that are associated with face-to-face encounters, such as whether an EP billed general office visit codes, outpatient visits, and surgical procedures. Under PQRS, if an EP bills for at least one service under the PFS during the performance period that is associated with face-to-face encounters and reports quality measures via claims or registries, then the EP is required to report at least one "cross-cutting" measure. EPs who do not meet these criteria are not required to report a cross-cutting measure. For the purposes of PQRS, telehealth services have not historically been included in the definition of face-to-face encounters. For more information, please see the CY 2016 PFS final rule for these discussions (80 FR 71140).

In the Stage 2 final rule (77 FR 54098 through 54099), the Medicare EHR Incentive Program established a significant hardship exception from the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act for EPs that lack face-to-face interactions with patients and those who lack the need to follow-up with patients. EPs with a primary specialty of anesthesiology, pathology or radiology listed in the Provider Enrollment, Chain, and Ownership System (PECOS) as of 6 months prior to the first day of the payment adjustment year automatically receive this hardship exemption (77 FR 54100). Codes associated with these specialties include 05 Anesthesiology, 22 Pathology, 30 Diagnostic Radiology, 36 Nuclear Medicine, 94 Interventional Radiology. EPs with a different specialty are also able to request this hardship exception through the hardship application process. However, telehealth services could be counted by EPs who choose to include these services within the definition of "seen by the EP" for the purposes of calculating patient encounters with the EHR Incentive Program (77 FR 53982).

In the MIPS and APMs RFI, we sought comments on MIPS eligible clinicians that should be considered non-patient-facing MIPS eligible clinicians and the criteria we should use to identify these MIPS eligible clinicians. Commenters were split when it came to defining and identifying non-patient-facing MIPS eligible clinicians. Many took a specialty-driven approach. Commenters generally did not support use of enrollment specialty codes alone, which is the approach used by the Medicare EHR Incentive Program. Commenters indicated that these codes do not necessarily delineate between the same specialists who may or may not have patient-facing interaction. One example is cardiologists who specialize in cardiovascular imaging which is also coded as cardiology. On the other hand, as one commenter mentioned, physicians with enrollment specialty codes other than "cardiology" (for example, internal medicine) may perform cardiovascular imaging services. Therefore, using the enrollment specialty code for cardiology to identify clinicians who typically do not provide patient-facing services would be both over-inclusive and under-inclusive. Other commenters identified specialty types that they believe should be considered non-patient-facing MIPS eligible clinicians. Specific specialty types included radiologists, anesthesiologists, nuclear cardiology or nuclear medicine physicians, and pathologists. Others pointed out that certain MIPS eligible clinicians may be primarily non-patient-facing MIPS eligible clinicians even though they practice within a traditionally patient-facing specialty. The MIPS and APMs RFI comments and listening sessions with medical societies representing non-patient-facing MIPS eligible clinicians specified radiology/imaging, anesthesiology, nuclear cardiology and oncology, and pathology as inclusive of non-patient-facing MIPS eligible clinicians. Commenters noted that roles within specific types of specialties may need to be further delineated between patient-facing and non-patient-facing MIPS eligible clinicians. An illustrative list of specific types of clinicians within the non-patient-facing spectrum include:

- Pathologists who may be primarily dedicated to working with local hospitals to identify early indicators related to evolving infectious diseases;
- Radiologists who primarily provide consultative support back to a referring physician or provide image interpretation and diagnosis versus therapy;
- Nuclear medicine physicians who play an indirect role in patient care, for example as a consultant to another physician in proper dose administration; or
- Anesthesiologists who are primarily providing supervision oversight to Certified Registered Nurse Anesthetists.

Some commenters believed that MIPS eligible clinicians should be defined as non-patient-facing MIPS eligible clinicians based on whether their billing indicates they provide face-to-face services. Commenters indicated that the use of specific HCPCS codes in combination with enrollment specialty codes, may be a more appropriate way to identify MIPS eligible clinicians that have no patient interaction.

After reviewing current policies, we propose to define a non-patient-facing MIPS eligible clinicians for MIPS at § 414.1305 as an individual MIPS eligible clinician or group that bills 25 or fewer patient-facing encounters during a performance period. We consider a patient-facing encounter as an instance in which the MIPS eligible clinician or group billed for services such as general office visits, outpatient visits, and surgical procedure codes under the PFS. We intend to publish the proposed list of patient-facing encounter codes on a CMS Web site similar to the way we currently publish the list of face-to-face encounter codes for PQRS. This proposal differs from the current PQRS policy in two ways. First, it creates a minimum threshold for the quantity of patient-facing encounters that MIPS eligible clinicians or groups would need to furnish to be considered patient-facing, rather than classifying MIPS eligible clinicians as patient-facing based on a single patient-facing encounter. Second, this proposal includes telehealth services in the definition of patient-facing encounters.

We believe that setting the non-patient-facing MIPS eligible clinician threshold for individual MIPS eligible clinician or group at 25 or fewer billed patient-facing encounters during a performance period is appropriate. We selected this threshold based on an analysis of non-patient-facing HCPCS codes billed by MIPS eligible clinicians. Using these codes and this threshold we identified approximately one quarter of MIPS eligible clinicians as non-patient-facing before MIPS exclusions, such as low-volume and newly-enrolled eligible clinician policies, were applied. The majority of clinicians enrolled in Medicare with specialties such as anesthesiology, nuclear medicine, and pathology were identified as non-patient-facing in this analysis. The addition of telemedicine to the analysis did not affect the outcome, as it created a less than 0.01 percent change in MIPS eligible clinicians categorized as non-patient-facing.

Therefore, this proposed approach allows the definition of non-patient-facing MIPS eligible clinicians, to include both MIPS eligible clinicians who practice within specialties traditionally considered non-patient-facing, as well as MIPS eligible clinicians who provide occasional patient-facing services that do not represent the bulk of their practices. This definition is also consistent with the statutory requirement that refers to professional types who typically furnish services that do not involve patient-facing interaction with a patient.

We also propose to include telehealth services in the definition of patient-facing encounters. Various MIPS eligible clinicians use telehealth services as an innovative way to deliver care to beneficiaries and we believe these services, while not furnished in-person, should be recognized as patient-facing. In addition, Medicare eligible telehealth services substitute for an in-person encounter and meet other site requirements under the PFS as defined at § 410.78.

The proposed addition of the encounter threshold for patient-facing MIPS eligible clinicians should minimize concerns that a MIPS eligible clinician could be misclassified as patient-facing as a result of providing occasional telehealth services that do not represent the bulk of their practice. Finally, this proposed definition of a non-patient-facing MIPS eligible clinician for MIPS can be consistently used throughout the MIPS program to identify those MIPS eligible clinicians for whom certain proposed requirements for patient-facing MIPS eligible clinicians (such as reporting cross-cutting measures) may not be meaningful.

We weighed several options when considering the appropriate definition of non-patient-facing MIPS eligible clinicians for MIPS; and some options were similar to those we considered in implementing the Medicare EHR Incentive Program. One option we considered was basing the non-patient-facing MIPS eligible clinician's definition on a set percentage of patient-facing encounters, such as 5 to 10 percent, that is tied to the same list of patient-facing encounter codes discussed in this section of the proposed rule. Another option we considered was the identification of non-patient-facing MIPS eligible clinicians for MIPS only by specialty, which might be a simpler approach. However, we do not consider this approach sufficient for identifying all the possible non-patient-facing MIPS eligible clinicians, as some patient-facing MIPS eligible clinicians practice in multi-specialty practices with non-patient-facing MIPS eligible clinician's practices with different specialties. We would likely have had to develop a separate process to identify non-patient-facing MIPS eligible clinicians in other specialties, whereas maintaining a single definition that is aligned across performance categories is simpler. Many comments from the MIPS and APMs RFI discouraged use of enrollment specialty alone. Additionally, we believe our proposal would allow us to more accurately identify MIPS eligible clinicians who are non-patient-facing by applying a threshold to recognize that a MIPS eligible clinician who furnishes almost exclusively non-patient-facing services should be treated as a non-patient-facing MIPS eligible clinicians despite furnishing a small number of patient-facing services. We seek comment on these alternative approaches.

In the MIPS and APMs RFI, we also requested comments on what types of measures and/or CPIAs (new or from other payment systems) we should use to assess non-patient-facing MIPS eligible clinicians' performance and how we should apply the MIPS performance categories to non-patient-facing MIPS eligible clinicians. Commenters were split on these subjects. A number of commenters stated that non-patient-facing MIPS eligible clinicians should be exempt from specific performance categories under MIPS or should be exempt from MIPS as a whole. Commenters who did not favor exemptions generally suggested that we focus on process measures and work with specialty societies to develop new, more clinically relevant measures for non-patient-facing MIPS eligible clinicians.

We took these stakeholder comments into consideration. We note that section 1848(q)(2)(C)(iv) of the Act does not grant the Secretary discretion to exempt non-patient-facing MIPS eligible clinicians from a performance category entirely, but rather to apply to the extent feasible and appropriate alternative measures or activities that fulfill the goals of the applicable performance category. However, we have placed safeguards to ensure that MIPS eligible clinicians, including non-patient facing, that do not have sufficient alternative measures that are applicable and available in a performance category are scored appropriately. We propose to apply the Secretary's authority under section 1848(q)(5)(F) of the Act to reweight such performance categories score to zero if there is no performance category score or to lower the weight of the quality performance category score if there are not at least three scored measures. Please refer to section II.E.6.b.(2)(b) in this proposed rule for details on the reweighting proposals. Accordingly, we have proposed alternative requirements for non-patient-facing MIPS eligible clinicians across this proposed rule (see sections II.E.5.b. II.E.5.e. and II.E.5.f. of this proposed rule for more details). While non-patient-facing MIPS eligible clinicians will not be exempt from any performance category under MIPS, we believe these alternative requirements fulfill the goals of the applicable performance categories and are in line with the commenters' desire to ensure that non-patient-facing MIPS eligible clinicians are not placed at an unfair disadvantage under the new program. The requirements also build on prior program components in meaningful ways and are meant to help us appropriately assess and incentivize non-patient-facing MIPS eligible clinicians. We request comments on these proposals.

c. MIPS Eligible Clinicians Who Practice in Critical Access Hospitals Billing Under Method II (Method II CAHs)

Section 1848(q)(6)(E) of the Act provides that the MIPS adjustment is applied to the amount otherwise paid under Part B for the items and services furnished by a MIPS eligible clinician during a year (beginning with 2019). In the case of MIPS eligible clinicians who practice in CAHs that bill under Method I ("Method I CAHs"), the MIPS adjustment would apply to payments made for items and services billed by MIPS eligible clinicians under the PFS, but it would not apply to the facility payment to the CAH itself. In the case of MIPS eligible clinicians who practice in Method II CAHs and have not assigned their billing rights to the CAH, the MIPS adjustment would apply in the same manner as for MIPS eligible clinicians who bill for items and services in Method I CAHs.

Under section 1834(g)(2) of the Act, a Method II CAH bills and is paid for facility services at 101 percent of its reasonable costs and for professional services at 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. In the case of MIPS eligible clinicians who practice in Method II CAHs and have assigned their billing rights to the CAHs, those professional services would constitute "covered professional services" under section 1848(k)(3)(A) of the Act because they are furnished by an eligible clinician and payment is "based on" the PFS. Moreover, this is consistent with the precedent CMS has established by applying the PQRS and EHR–MU adjustments to Method II CAH payments. Therefore, we propose the MIPS adjustment does apply to Method II CAH payments under section 1834(g)(2)(B) of the Act when MIPS eligible clinicians who practice in Method II CAHs have assigned their billing rights to the CAH. We request comments on this proposal.

d. MIPS Eligible Clinicians Who Practice in Rural Health Clinics (RHCs) and/or Federally Qualified Health Centers (FQHCs)

As noted previously in this proposed rule, section 1848(q)(6)(E) of the Act provides that the MIPS adjustment is applied to the amount otherwise paid under Part B with respect to the items and services furnished by a MIPS eligible clinician during a year. Some eligible clinician s may not receive MIPS adjustments due to their billing methodologies. If a MIPS eligible clinician furnishes items and services in an RHC and/or FQHC and the RHC and/or FQHC bills for those items and services under the RHC's or FQHC's all-inclusive payment methodology, the MIPS adjustment would not apply to the facility payment to the RHC or FQHC itself. However, if a MIPS eligible clinician furnishes other items and services in an RHC and/or FQHC and bills for those items and services under the PFS, the MIPS adjustment would apply to payments made for items and services. Accordingly, the MIPS eligible clinician would need to meet the applicable MIPS reporting requirements to avoid a downward MIPS adjustment to payments made for items and services billed by the MIPS eligible clinician under the PFS. Therefore, we propose services rendered by an eligible clinician that are payable under the RHC or FQHC methodology would not be subject to the MIPS payments adjustments. However, these eligible clinicians have the option to voluntarily report on applicable measures and activities for MIPS and the data received would not be used to assess their performance for the purpose of the MIPS adjustment. We request comments on this proposal.

e. Group Practice (Group)

Section 1848(q)(1)(D) of the Act, requires the Secretary to establish and apply a process that includes features of the PQRS group practice reporting option (GPRO) established under section 1848(m)(3)(C) of the Act for MIPS eligible clinicians in a group for purposes of assessing performance in the quality performance category. In addition, it gives the Secretary the discretion to do so for the other three performance categories. Additionally, we will assess performance either for individual MIPS eligible clinicians or for groups. As discussed in section II.E.2.b of this proposed rule, we propose to define a group at § 414.1305 as a single Taxpayer Identification Number (TIN) with two or more MIPS eligible clinicians, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN. Also, as outlined in section II.E.2.c. of this proposed rule, we propose to define an APM Entity group at § 414.1305 identified by a unique APM participant identifier.

2. MIPS Eligible Clinician Identifier

To support MIPS eligible clinicians reporting to a single comprehensive and cohesive MIPS program, we need to align the technical reporting requirements from PQRS, VM, and EHR–MU into one program. This requires an appropriate MIPS eligible clinician identifier. We currently use a variety of identifiers to assess an individual eligible clinician or group under different programs. For example, under the PQRS for individual reporting, CMS uses a combination of TIN and NPI to assess eligibility and participation, where each unique TIN and NPI combination is treated as a distinct eligible clinician and is separately assessed for purposes of the program. Under the PQRS GPRO, eligibility and participation are assessed at the TIN level. Under the Medicare EHR Incentive Program, we utilize the NPI to assess eligibility and participation. And under the VM, performance and payment adjustments are assessed at the TIN level. Additionally, for APMs such as the Pioneer Accountable Care Organization (ACO) Model, we also assign a program-specific identifier (in the case of the Pioneer ACO Model, an ACO ID) to the organization(s), and associate that identifier with individual eligible clinicians who are, in turn, identified through a combination of a TIN and an NPI.

In the MIPS and APMs RFI, we sought comments on which specific identifier(s) should be used to identify a MIPS eligible clinician for purposes of determining eligibility, participation, and performance under the MIPS performance categories. In addition, we requested comments pertaining to what safeguards should be in place to ensure that MIPS eligible clinicians do not switch identifiers to avoid being considered "poor-performing" and comments on what safeguards should be in place to address any unintended consequences, if the MIPS eligible clinician identifier were a unique TIN/NPI combination, to ensure an appropriate assessment of the MIPS eligible clinician's performance. In the MIPS and APMs RFI, we sought comment on using a MIPS eligible clinician's TIN, NPI, or TIN/NPI combination as potential MIPS eligible clinician identifiers, or creating a unique MIPS eligible clinician identifier. The commenters did not demonstrate a consensus on a single best identifier.

Commenters favoring the use of the MIPS eligible clinician's TIN recommended that MIPS eligible clinicians should be associated with the TIN used for receiving payment from CMS claims. They further commented that this approach will deter MIPS eligible clinicians from "gaming" the system by switching to a higher performing group. Under this approach, commenters suggest that MIPS eligible clinicians who bill under more than one TIN can be assigned the performance and payment adjustment for the primary practice based upon majority of dollar amount of claims or encounters from the prior year.

Other commenters supported using unique TIN and NPI combinations to identify MIPS eligible clinicians. Commenters suggested many eligible clinicians are familiar with using TIN and NPI together from PQRS and other CMS programs. Commenters also noted this approach can calculate performance for multiple unique TIN/NPI combinations for those MIPS eligible clinicians who practice under more than one TIN. Commenters who supported the TIN/NPI also believe this approach enables greater accountability for individual MIPS eligible clinicians beyond what might be achieved when using TIN as an identifier and would provide a safeguard from MIPS eligible clinicians changing their identifier to avoid payment penalties.

Some commenters supported the use of only the NPI as the MIPS identifier. They believe this approach would best provide for individual accountability for quality in MIPS while minimizing potential confusion because providers do not generally change their NPI over time. Supporters of using the NPI only as the MIPS identifier also commented that this approach would be simplest for administrative purposes. These commenters also note the continuity inherent with the NPI would address the safeguard issue of providers attempting to change their identifier for MIPS performance purposes.

In the MIPS and APMs RFI, we also solicited feedback on the potential for creating a new MIPS identifier for the purposes of identifying MIPS eligible clinicians within the MIPS program. In response, many commenters indicated they would not support a new MIPS identifier. Commenters generally expressed concern that a new identifier for MIPS would only add to administrative burden, create confusion for MIPS eligible clinicians and increase reporting errors.

After reviewing the comments, we are not proposing to create a new MIPS eligible clinician identifier. However, we appreciate the various ways a MIPS eligible clinician may engage with MIPS, either individually or through a group. Therefore, we are proposing to use multiple identifiers that allow MIPS eligible clinicians to be measured as an individual or collectively through a group's performance. We also propose that the same identifier be used for all four performance categories; for example, if a group is submitting information collectively, then it must be measured collectively for all four MIPS performance categories: Quality, resource use, CPIA, and advancing care information. As discussed later in the CPS methodology section II.E.6. of this proposed rule, while we have multiple identifiers for participation and performance, we proposed to use a single identifier, TIN/NPI, for applying the payment adjustment, regardless of how the MIPS eligible clinician is assessed. Specifically, if the MIPS eligible clinician is identified for performance only using the TIN, when applying the payment adjustment we propose to use the TIN/NPI. We request comments on these proposals.

a. Individual Identifiers

We propose to use a combination of billing TIN/NPI as the identifier to assess performance of an individual MIPS eligible clinician. Similar to PQRS, each unique TIN/NPI combination would be considered a different MIPS eligible clinician, and MIPS performance would be assessed separately for each TIN under which an individual bills. While we considered using the NPI only, we believe TIN/NPI is a better approach for MIPS. Both TIN and NPI are needed for payment purposes and using a combination of billing TIN/NPI as the MIPS eligible clinician identifier allows us to match MIPS performance and payment adjustments with the appropriate practice, particularly for MIPS eligible clinicians that bill under more than one TIN. In addition, using TIN/NPI also provides the flexibility to allow individual MIPS eligible clinician and group reporting, as the group identifiers being proposed also include TIN as part of the identifier. We recognize that TIN/NPI is not a static identifier and can change if an individual MIPS eligible clinician changes practices and/or if a group merges with another between the performance period and payment adjustment period. Section II.E.5.h. of this proposed rule describes in more detail how we propose to match performance in cases where the TIN/NPI changes. We request comments on this proposal.

b. Group Identifiers for Performance

We propose the following way a MIPS eligible clinician may have their performance assessed as part of a group under MIPS. We propose to use a group's billing TIN to identify a group. This approach has been used as a group identifier for both PQRS and VM. The use of the TIN would significantly reduce the participation burden that could be experienced by large groups. Additionally, the utilization of the TIN benefits large and small practices by allowing such entities to submit performance data one time for their group and develop systems to improve performance. Groups that report on quality performance measures through certain data submission methods must register in order to participate in MIPS as described in section II.E.5.b. of this proposed rule.

We are proposing to codify the definition of a group at § 414.1305 as a group that would consist of a single TIN with two or more MIPS eligible clinicians (as identified by their individual NPI) who have reassigned their billing rights to the TIN. We request comments on this proposal.

c. APM Entity Group Identifier for Performance

We propose the following way to identify a group to support APMs (see section II.F.5.b. of this proposed rule). To ensure we have accurately captured all of the eligible clinicians identified as participants that are participating in the APM Entity, we propose that each eligible clinician who is a participant of an APM Entity would be identified by a unique APM participant identifier. The unique APM participant identifier would be a combination of four identifiers: (1) APM Identifier (established by CMS; for example, XXXXXX); (2) APM Entity identifier (established under the APM by CMS; for example, AA00001111); (3) TIN(s) (9 numeric characters; for example, XXXXXXXXX); (4) EP NPI (10 numeric characters; for example, 1111111111). For example, an APM participant identifier could be APM XXXXXX, APM Entity AA00001111, TIN-XXXXXXXXX, NPI-11111111111.

We are proposing to codify the definition of an APM Entity group at § 414.1305 as an APM Entity identified by a unique APM participant identifier. We request comments on these proposals. See section II.E.5.h. of this rule for proposed policies regarding requirements for APM Entity groups under MIPS.

3. Exclusions

a. New Medicare-Enrolled Eligible Clinician

Section 1848(q)(1)(C)(v) of the Act provides that in the case of a professional who first becomes a Medicare-enrolled eligible clinician during the performance period for a year (and had not previously submitted claims under Medicare either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier), that the eligible clinician will not be treated as a MIPS eligible clinician until the subsequent year and performance period for that year. In addition, section 1848(q)(1)(C)(vi) of the Act clarifies that individuals who are not deemed MIPS eligible clinicians for a year will not receive a MIPS adjustment factor (or additional MIPS adjustment factor). Accordingly, we propose at § 414.1305 that a new Medicare-enrolled eligible clinician be defined as a professional who first becomes a Medicare-enrolled eligible clinician within the PECOS during the performance period for a year and who has not previously submitted claims as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier. These eligible clinicians will not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year. As discussed in section II.E.4. of this proposed rule, we are proposing that the MIPS performance period would be the calendar year (January 1 through December 31) 2 years prior to the year in which the MIPS adjustment is applied. For example, an eligible clinician who newly enrolls in Medicare within PECOS in 2017 would not be required to participate in MIPS in 2017, and he or she would not receive a MIPS adjustment in 2019. The same eligible clinician would be required to participate in MIPS in 2018 and would receive a MIPS adjustment in 2020, and so forth. In addition, in the case of items and services furnished during a year by an individual who is not an MIPS eligible clinician, there will not be a MIPS adjustment factor (or additional MIPS adjustment factor) applied for that year. We also propose at § 414.1310(d) that in no case would a MIPS adjustment factor (or additional MIPS adjustment factor) apply to the items and services furnished by new Medicare-enrolled eligible clinicians.

We request comments on these proposals.

b. Qualifying APM Participants (QP) and Partial Qualifying APM Participant (Partial QP)

Sections 1848(q)(1)(C)(ii)(I) and (II) of the Act provide that the definition of a MIPS eligible clinician does not include, for a year, an eligible clinician who is a Qualifying APM Participant (QP) (as defined in section 1833(z)(2) of the Act) or a Partial Qualifying APM Participant (Partial QP) (as defined in section 1848(q)(1)(C)(iii) of the Act) who does not report on the applicable measures and activities that are required under MIPS. Section II.F.5. of this proposed rule provides detailed information on the determination of QPs and Partial QPs.

We propose that the definition of a MIPS eligible clinician at § 414.1310 does not include qualifying APM participants (defined at § 414.1305) and Partial QPs defined at § 414.1305 who do not report on applicable measures and activities that are required to be reported under MIPS for any given performance period. Partial QPs will have the option to elect whether or not to report under MIPS, which determines whether or not they will be subject to MIPS adjustments. Please refer to the section II.F.5.c. of this proposed rule where this election is discussed in greater detail. We request comments on this proposal.

c. Low-Volume Threshold

Section 1848(q)(1)(C)(ii)(III) of the Act provides that the definition of a MIPS eligible clinician does not include MIPS eligible clinicians who are below the low-volume threshold selected by the Secretary under section 1848(q)(1)(C)(iv) of the Act for a given year. Section 1848(q)(1)(C)(iv) of the Act requires the Secretary to select a low-volume threshold to apply for the purposes of this exclusion which may include one or more of the following: (1) The minimum number, as determined by the Secretary, of Part B-enrolled individuals who are treated by the MIPS eligible clinician for a particular performance period; (2) the minimum number, as determined by the Secretary, of items and services furnish to Part B-enrolled individuals by the MIPS eligible clinician for a particular performance period; and (3) the minimum amount, as determined by the Secretary, of allowed charges billed by the MIPS eligible clinician for a particular performance period.

We propose at § 414.1305 to define MIPS eligible clinicians or groups who do not exceed the low-volume threshold as an individual MIPS eligible clinician or group who, during the performance period, have Medicare billing charges less than or equal to $10,000 and provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. We believe this strategy is value-oriented as it retains as MIPS eligible clinicians those MIPS eligible clinicians who are treating relatively few beneficiaries, but engage in resource intensive specialties, or those treating many beneficiaries with relatively low-priced services. By requiring both criteria be met, we can meaningfully measure the performance and drive quality improvement across the broadest range of MIPS eligible clinician types and specialties. Conversely, it excludes MIPS eligible clinicians who do not have a substantial quantity of interactions with Medicare beneficiaries or furnish high cost services.

In developing this proposal we considered using items and services furnished to Part B-enrolled individuals by the MIPS eligible clinician for a particular performance period rather than patients but a review of the data reflected there were nominal differences between the two methods. We plan to monitor the proposed requirement and anticipate that the specific thresholds will evolve over time. We request comments on this proposal including alternative patient threshold, case thresholds, and dollar values.

d. Group Reporting

(1) Background

As noted above, section 1848(q)(1)(D) of the Act, requires the Secretary to establish and apply a process that includes features of the PQRS group practice reporting option (GPRO) established under section 1848(m)(3)(C) of the Act for MIPS eligible clinicians in a group for the purpose of assessing performance in the quality category and give the Secretary the discretion to do so for the other performance categories. The process established for purposes of MIPS must, to the extent practicable, reflect the range of items and services furnished by the MIPS eligible clinicians in the group. We believe this means that the process established for purposes of MIPS should, to the extent practicable, encompass elements that enable MIPS eligible clinicians in a group to meet reporting requirements that reflect the range of items and services furnished by the MIPS eligible clinicians in the group. At § 414.1310(e) we propose requirements for groups. For purposes of section 1848(q)(1)(D) of the Act, at § 414.1310(e)(1) we propose the following way for individual MIPS eligible clinicians to have their performance assessed as a group: As part of a single TIN associated with two or more MIPS eligible clinicians, as identified by a NPI, that have their Medicare billing rights reassigned to the TIN (as discussed further in section II.E.1.f. of this proposed rule).

In order to have its performance assessed as a group, at § 414.1310(e)(2) we propose a group must meet the proposed definition of a group at all times during the performance period for the MIPS payment year. Additionally, at § 414.1310(e)(3) we propose in order to have their performance assessed as a group, individual MIPS eligible clinicians within a group must aggregate their performance data across the TIN. At § 414.1310(e)(3), we propose a group that elects to have its performance assessed as a group would be assessed as a group across all four MIPS performance categories. For example, if a group submits data for the quality performance category as a group, CMS would assess them as a group for the remaining three performance categories. We solicit public comments on the proposal regarding how groups will be assessed under MIPS.

(2) Registration

Under the PQRS, groups are required to complete a registration process to participate in PQRS as a group. During the implementation and administration of PQRS, we received feedback from stakeholders regarding the registration process for the various methods available for data submission. Stakeholders indicated that the registration process was burdensome and confusing. Additionally, we discovered that during the registration process when groups are required to select their group submission mechanism, groups sometimes selected the option not applicable to their group, which has created issues surrounding the mismatch of data. Unreconciled data mismatching can impact the quality of data. In order to address this issue, we are proposing to eliminate a registration process for groups submitting data using third party entities. When groups submit data utilizing third party entities, such as a qualified registry, health IT vendor, or QCDR, we are able to obtain group information from the third party entity and discern whether the data submitted represents group submission or individual submission once the data is submitted.

At § 414.1310(e)(5), we propose that a group must adhere to an election process established and required by CMS, as described below. We do not propose to require groups to register to have their performance assessed as a group except for groups submitting data on performance measures via participation in the CMS Web Interface or groups electing to report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey for the quality performance category as described further in section II.E.5.b. of this proposed rule. For all other data submission methods, groups must work with appropriate third party entities to ensure the data submitted clearly indicates that the data represent a group submission rather than an individual submission. In order for groups to elect participation via the CMS Web Interface or administration of the CAHPS for MIPS survey, we propose that such groups must register by June 30 of the applicable 12-month performance period (that is, June 30, 2017, for performance periods occurring in 2017). For the criteria regarding group reporting applicable to the four MIPS performance categories, see section II.E.5.a. of this proposed rule.

e. Virtual Groups

(1) Implementation

Section 1848(q)(5)(I) of the Act establishes the use of voluntary virtual groups for certain assessment purposes. The statute requires the establishment and implementation of a process that allows an individual MIPS eligible clinician or a group consisting of not more than 10 MIPS eligible clinicians to elect to form a virtual group with at least one other such individual MIPS eligible clinician or group of not more than 10 MIPS eligible clinicians for a performance period of a year. As determined in statute, individual MIPS eligible clinicians and groups forming virtual groups are required to make such election prior to the start of the applicable performance period under MIPS and cannot change their election during the performance period. As discussed in section II.E.4. of this proposed rule, we are proposing that the performance period would be based on a calendar year.

As we assessed the timeline for the establishment and implementation of virtual groups and applicable election process and requirements for the first performance period under MIPS, we identified significant barriers regarding the development of a technological infrastructure required for successful implementation and the operationalization of such provisions that would negatively impact the execution of virtual groups as a conducive option for MIPS eligible clinicians or groups. The development of an electronic system before policies are finalized poses several risks, particularly relating to the impediments of completing and adequately testing the system before execution and assuring that any change in policy made during the rulemaking process are reflected in the system and operationalized accordingly. We believe that it would be exceedingly difficult to make a successful system to support the implementation of virtual groups and given these factors, such implementation would compromise not only the integrity of the system, but the intent of the policies.

Additionally, we recognize that it would be impossible for us to develop an entire infrastructure for electronic transactions pertaining to an election process, reporting of data, and performance measurement before the start of the performance period beginning on January 1, 2017. Moreover, the actual implementation timeframe would be more condensed given that the development, testing, and execution of such a system would need to be completed months in advance of the beginning of the performance period in order to provide MIPS eligible clinicians and groups with an election period.

During the implementation and ongoing functionality of other programs such as PQRS, Medicare EHR Incentive Program, and VM, we received feedback from stakeholders regarding issues they encountered when submitting reportable data for these programs. With virtual groups as a new option, we want to minimize potential issues for end-users and implement a system that encourages and enables MIPS eligible clinicians and groups to participate in a virtual group. A web-based registration process, which would simplify and streamline the process for participation, is our preferred approach. Given the aforementioned dynamics discussed in this section, implementation for the calendar year 2017 performance period is infeasible as a result of the insufficient timeframe to develop a web-based registration process. We have assessed alternative approaches for the first year only, such as an email registration process, but believe that there are limitations and potential risks for numerous errors, such as submitted information being incomplete or not in the required format. A manual verification process would cause a significant delay in verifying registration due to the lack of an automated system to ensure the accuracy of the type of information submitted that is required for registration. We believe that an email registration process could become cumbersome and a burden for groups to pursue participation in a virtual group. Implementation of a web-based registration system for calendar year 2018 would provide the necessary time to establish and implement an election process and requirements applicable to virtual groups, and enable proper system development and operations. We intend to implement virtual groups for the 2018 calendar year performance period and we intend to address all of the requirements pertaining to virtual groups in future rulemaking. We request comments on factors we should consider regarding the establishment and implementation of virtual groups.

(2) Election Process

Section 1848(q)(5)(I)(iii)(I) of the Act provides that the election process must occur prior to the performance period and may not be changed during the performance period. We propose to establish an election process that would end on June 30 of a calendar year preceding the applicable performance period. During the election process, we propose that individual MIPS eligible clinicians and groups electing to be a virtual group would be required to register in order to submit reportable data. Virtual groups would be assessed across all four MIPS performance categories. In future rulemaking, we intend to address all elements relating to the election process. We solicit public comments on this proposal. Future rulemaking will outline the criteria and requirements regarding the formation of virtual groups.

4. MIPS Performance Period

MIPS incorporates many of the requirements of several programs into a single, comprehensive program. This consolidation includes key policy goals as common themes across multiple categories such as quality improvement, patient and family engagement, and care coordination through interoperable health information exchange. However, each of these legacy programs included different eligibility requirements, reporting periods, and systems for providers seeking to participate. This means that we must balance potential impacts of changes to systems and technical requirements in order to successfully synchronize reporting, as noted in the discussion regarding the definition of a MIPS eligible clinician in section II.E.1.a. of this proposed rule. We must take operational feasibility, systems impacts, and education and outreach on participation requirements into account in developing technical requirements for participation. One area where this is particularly important is in the definition of a performance period.

MIPS applies to payments for items and services furnished on or after January 1, 2019. Section 1848(q)(4) of the Act requires the Secretary to establish a performance period (or periods) for a year (beginning with 2019). Such performance period (or periods) must begin and end prior to such year and be as close as possible to such year. In addition, section 1848(q)(7) of the Act provides that, not later than 30 days prior to January 1 of the applicable year, the Secretary must make available to each MIPS eligible clinician the MIPS adjustment (and, as applicable, the additional MIPS adjustment) applicable to the MIPS eligible clinician for items and services furnished by the MIPS eligible clinician during the year.

We considered various factors when developing the policy for the MIPS performance period. Stakeholders have stated that having a performance period as close to when payments are adjusted is beneficial, even if such period would be less than a year. We have also received feedback from stakeholders that they prefer having a 1 year performance period and have further suggested that the performance period start during the calendar year. For example, having the performance period occurring from July 1 through June 30. We additionally considered operational factors, such as that a 1 year performance period may be beneficial for all four performance categories because many measures and activities cannot be reported in a shorter time frame. We also considered that data submission activities and claims for items and services furnished during the 1 year performance period (which could be used for claims- or administrative claims-based quality or resource use measures) may not be fully processed until the following year.

These circumstances will require adequate lead time to collect performance data, assess performance, and compute the MIPS adjustment so the applicable MIPS adjustment can be made available to each MIPS eligible clinician at least 30 days prior to when the payment adjustment is applied each year. For 2019, these actions will occur during 2018. In other payment systems, we have used claims that are processed within a specified time period after the end of the performance period, such as 60 or 90 days, for assessment of performance and application of the payment adjustment. For MIPS, we propose at § 414.1325(g)(2) to use claims that are processed within 90 days, if operationally feasible, after the end of the performance period for purposes of assessing performance and computing the MIPS payment adjustment. If we determine that it is not operationally feasible to have a claims data run-out for the 90-day timeframe, then we would utilize a 60-day duration.

This proposal does not affect the performance period per se, but rather the deadline by which claims for items and services furnished during the performance period need to be processed for those items and services to be included in our calculation. To the extent that claims are used for submitting data on MIPS measures and activities to us, such claims would have to be processed by no later than 90 days after the end of the applicable performance period, in order for information on the claims to be included in our calculations. As noted above, if we determine that it is not operationally feasible to have a claims data run-out for the 90-day timeframe, then we will utilize a 60-day duration. As an alternative to the above proposal, we also considered using claims that are paid within 60 days after 2017, for assessment of performance and application of the MIPS payment adjustment for 2019. We are seeking comment on both approaches.

Given the need to collect and process information, we propose at § 414.1320 that for 2019 and subsequent years, the performance period under MIPS would be the calendar year (January 1 through December 31) 2 years prior to the year in which the MIPS adjustment is applied. For example, the performance period for the 2019 MIPS adjustment would be the full calendar year 2017, that is, January 1, 2017 through December 31, 2017. We propose to use the 2017 performance year for the 2019 payment adjustment consistent with other CMS programs. This approach allows for a full year of measurement and sufficient time to base adjustments on complete and accurate information.

For individual MIPS eligible clinicians and group practices with less than 12 months of performance data to report, such as when a MIPS eligible clinician switches practices during the performance period or when a MIPS eligible clinician may have stopped practicing for some portion of the performance period (for example, a MIPS eligible clinician who is on maternity leave or has an illness), we propose that the individual MIPS eligible clinician or group would be required to report all performance data available from the performance period. Specifically, if a MIPS eligible clinician is reporting as an individual, they would report all partial year performance data. Alternatively, if the MIPS eligible clinician is reporting with a group, then the group would report all performance data available from the performance period, including partial year performance data available for the individual MIPS eligible clinician.

Under this approach, MIPS eligible clinicians with partial year performance data could achieve a positive, neutral, or negative MIPS adjustment based on their performance data. We propose this approach in order to incentivize accountability for all performance during the performance period. Two policies will help minimize the impact of partial year data. First, MIPS eligible clinicians with volume below the low-volume threshold would be excluded from any payment adjustments. Second, MIPS eligible clinicians who report measures, yet have insufficient sample size, would not be scored on those measures and activities refer to section II.E.6. of this proposed rule for further details.

To potentially refine this proposal in future years, we seek comment on methods to identify accurately MIPS eligible clinicians with less than 12-month reporting periods, notwithstanding common and expected absences due to illness, vacation, or holiday leave. Reliable identification of these MIPS eligible clinicians will allow us to analyze the characteristics of this MIPS eligible clinicians' patient population and better understand how a reduced reporting period impacts performance.

We also seek public comment on an alternative approach for future years for assessment of individual MIPS eligible clinicians with less than 12 months of performance data in the performance year. For example, if we can identify such MIPS eligible clinician's and confirm there are data issues that led to invalid performance calculations, then we could score the MIPS eligible clinician with a CPS equal to the performance threshold, which would result in a zero payment adjustment. We note this approach would not assess a MIPS eligible clinicians' performance for partial-year performance data. We do not believe that consideration of partial year performance is necessary for assessment of groups, which should have adequate coverage across MIPS eligible clinicians to provide valid performance calculations.

We also seek comment on reasonable thresholds for considering performance to be less than 12 months. For example, we expect that some MIPS eligible clinicians will take leave related to illness, vacation, and holidays. We would not anticipate applying special policies for lack of performance related to these common and expected absences assuming MIPS eligible clinicians' quality reporting includes measures with sufficient sample size to generate valid and reliable scores. We seek comment on how to account for MIPS eligible clinicians with extended leave that may affect measure sample size.

We request comments on these proposals and approaches.

5. MIPS Category Measures and Activities

a. Performance Category Measures and Reporting

(1) Statutory Requirements

Section 1848(q)(2)(A) of the Act requires the Secretary to use four performance categories in determining each MIPS eligible clinician's CPS under the MIPS: Quality; resource use; CPIA; and advancing care information. Section 1848(q)(2)(B) of the Act, subject to section 1848(q)(2)(C) of the Act, describes the measures and activities that, for purposes of the MIPS performance standards, must be specified under each performance category for a performance period.

Section 1848(q)(2)(B)(i) of the Act describes the measures and activities that must be specified under the MIPS quality performance category as the quality measures included in the annual final list of quality measures published under section 1848(q)(2)(D)(i) of the Act and the list of quality measures described in section 1848(q)(2)(D)(vi) of the Act used by QCDRs under section 1848(m)(3)(E) of the Act. Under section 1848(q)(2)(C)(i) of the Act, the Secretary must, as feasible, emphasize the application of outcome-based measures in applying section 1848(q)(2)(B)(i) of the Act. Under section 1848(q)(2)(C)(iii) of the Act, the Secretary may also use global measures, such as global outcome measures and population-based measures, for purposes of the quality performance category. Section 1848(q)(2)(B)(ii) of the Act describes the measures and activities that must be specified under the resource use performance category as the measurement of resource use for the performance period under section 1848(p)(3) of the Act, using the methodology under section 1848(r) of the Act as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Part D.

Section 1848(q)(2)(C)(ii) of the Act allows the Secretary to use measures from other CMS payment systems, such as measures for inpatient hospitals, for purposes of the quality and resource use performance categories, except that the Secretary may not use measures for hospital outpatient departments, other than in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. This proposed rule seeks comment on how it might be feasible and when it might be appropriate to incorporate measures from other systems into MIPS for clinicians that work in facilities such as inpatient hospitals. For example, it may be appropriate to use such measures when other applicable measures are not available for individual MIPS eligible clinicians or when strong payment incentives are tied to measure performance, either at the facility level or with employed or affiliated MIPS eligible clinicians.

Section 1848(q)(2)(B)(iii) of the Act describes the measures and activities that must be specified under the CPIA performance category as CPIAs under subcategories specified by the Secretary for the performance period, which must include at least the subcategories specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act. Section 1848(q)(2)(C)(v)(III) of the Act defines a CPIA as an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act requires the Secretary to give consideration to the circumstances of small practices (consisting of 15 or fewer professionals) and practices located in rural areas and geographic HPSAs in establishing CPIAs.

Section 1848(q)(2)(B)(iv) of the Act describes the measures and activities that must be specified under the advancing care information performance category as the requirements established for the performance period under section 1848(o)(2) for determining whether an eligible clinician is a meaningful EHR user.

As discussed in section II.E.1.b. of this proposed rule, section 1848(q)(2)(C)(iv) of the Act requires the Secretary to give consideration to the circumstances of non-patient facing MIPS eligible clinicians in specifying measures and activities under the MIPS performance categories and allows the Secretary, to the extent feasible and appropriate, to take those circumstances into account and apply alternative measures or activities that fulfill the goals of the applicable performance category. In doing so, the Secretary is required to consult with non-patient facing professionals.

Section 101(b) of MACRA amends certain provisions of section 1848(k), (m), (o), and (p) of the Act to generally provide that the Secretary will carry out such provisions in accordance with section 1848(q)(1)(F) of the Act for purposes of MIPS. Section 1848(q)(1)(F) of the Act provides that, in applying a provision of section 1848(k), (m), (o), and (p) of the Act for purposes of MIPS, the Secretary must adjust the application of the provision to ensure that it is consistent with the MIPS requirements and must not apply the provision to the extent that it is duplicative with a MIPS provision.

(2) Submission Mechanisms

We propose at § 414.1325(a) that individual MIPS eligible clinicians and groups would be required to submit data on measures and activities for the quality, CPIA and advancing care information performance categories. As proposed at § 414.1325(f), we do not propose any data submission requirements for the resource use performance category and for certain quality measures used to assess performance on the quality performance category and for certain activities in the CPIA performance category. For the resource use performance category, we propose that each individual MIPS eligible clinician's and group's resource use performance would be calculated using administrative claims data. As a result, individual MIPS eligible clinicians and groups would not be required to submit any additional information for the resource use performance category. In addition, we would be using administrative claims data to calculate performance on a subset of the MIPS quality measures and the CPIA performance category. For this subset of quality measures and CPIAs, MIPS eligible clinicians and groups would not be required to submit additional information. For individual clinicians and groups that are not MIPS eligible clinicians, such as physical therapists, but elect to report to MIPS, we would calculate administrative claims resource use measures and quality measures, if data is available. We are proposing multiple data submission mechanisms for MIPS as outlined in Tables 1 and 2 to provide MIPS eligible clinicians with flexibility to submit their MIPS measures and activities in a manner that best accommodates the characteristics of their practice. We note that other terms have been used for these submission mechanisms in earlier programs and in industry. As a result, the terms used for the submission mechanisms may be refined in the final rule for clarity.

TABLE 1: Proposed Data Submission Mechanisms for MIPS Eligible Clinicians Reporting Individually as TIN/NPI

Performance Category/Submission Combinations Accepted	Individual Reporting Data submission Mechanisms
Quality	Claims QCDR Qualified registry EHR Administrative claims (no submission required)
Resource Use	Administrative claims (no submission required)
Advancing Care Information	Attestation QCDR Qualified registry EHR
CPIA	Attestation QCDR Qualified registry EHR Administrative claims (if technically feasible, no submission required)

TABLE 2: Proposed Data Submission Mechanisms for Groups

Performance Category/Submission Combinations Accepted	Group Practice Reporting Data Submission Mechanisms
Quality	QCDR Qualified registry EHR CMS Web Interface (groups of 25 or more) CMS-approved survey vendor for CAHPS for MIPS (must be reported in conjunction with another data submission mechanism.) and Administrative claims (no submission required)
Resource Use	Administrative claims (no submission required)
Advancing Care Information	Attestation QCDR Qualified registry EHR CMS Web Interface (groups of 25 or more)
CPIA	Attestation QCDR Qualified registry EHR CMS Web Interface (groups of 25 or more) Administrative claims (if technically feasible, no submission required)

We propose at § 414.1325(d) that MIPS eligible clinicians and groups may elect to submit information via multiple mechanisms; however, they must use the same identifier for all performance categories and they may only use one submission mechanism per category. For example, a MIPS eligible clinician could use one submission mechanism for sending quality measures and another for sending CPIA data, but a MIPS eligible clinician could not use two submission mechanisms for a single category such as submitting three quality measures via claims and three quality measures via registry. We believe the proposal to allow multiple mechanisms, while restricting the number of mechanisms per category, offers flexibility without adding undue complexity.

For individual MIPS eligible clinicians, we propose at § 414.1325(b), that an individual MIPS eligible clinician may choose to submit their quality, CPIA, and advancing care information data using qualified registry, QCDR, or EHR submission mechanisms. Furthermore, we propose at § 414.1400 that a qualified registry, health IT vendor, or QCDR could submit data on behalf of the MIPS eligible clinician for the three performance categories: Quality, CPIA, and advancing care information. As described in section II.E.9. of this proposed rule, these third party intermediaries would have to be qualified to submit for each of the performance categories. Additionally, we propose at § 414.1325(b)(4) and (5) that individual MIPS eligible clinicians may elect to report quality information via Medicare Part B claims and their CPIA and advancing care information performance category data through attestation.

For groups that are not reporting through the APM scoring standard, we propose at § 414.1325(c) that these groups may choose to submit their MIPS quality, CPIA, and advancing care information data using qualified registry, QCDR, EHR, or CMS Web Interface (for groups of 25+ MIPS eligible clinicians) submission mechanisms. Furthermore, we propose at § 414.1400 that a qualified registry, health IT vendor that obtains data from a MIPS eligible clinician's CEHRT, or QCDR could submit data on behalf of the group for the three performance categories: Quality, CPIA, and advancing care information. Additionally, groups may elect to submit their CPIA or advancing care information performance category data through attestation.

For those MIPS eligible clinicians participating in an APM that uses the APM scoring standard, we refer readers to section II.E.5.h. of this proposed rule, which describes how certain APM Entities submit data to MIPS, including separate approaches to the quality and resource use performance categories for APMs.

We propose one exception to the requirement for one reporting mechanism per category. Groups consisting of two or more eligible clinicians that elect to include CAHPS for MIPS as a quality measure must use a CMS-approved survey vendor. Their other quality information may be reported by any single one of the other proposed submission mechanisms.

While we allow MIPS eligible clinicians and groups to submit data for different performance categories via multiple submission mechanisms, we encourage MIPS eligible clinicians to submit MIPS information for the CPIA and advancing care information performance categories through the same reporting mechanism that is used for quality reporting. We believe it would reduce administrative burden and would simplify the data submission process for MIPS eligible clinicians by having a single reporting mechanism for all three performance categories for which MIPS eligible clinicians would be required to submit data: Quality, CPIA and advancing care information. However, we were concerned that not all third party entities would be able to implement the changes necessary to support reporting on all categories in the first year. We seek comments for future rulemaking on whether we should propose requiring health IT vendors, QCDRs and qualified registries to have the capability to submit data for all MIPS performance categories.

As we noted in this section of the proposed rule, we propose that MIPS eligible clinicians may report measures and activities using different submission methods across the performance categories. As we gain experience under MIPS, we anticipate that in future years it may be beneficial and reduce burden on MIPS eligible clinicians to require data for multiple performance categories to come through a single submission mechanism.

Further, we will be flexible in implementing MIPS. For example, if a MIPS eligible clinician submits data via multiple submission mechanisms (for example, registry and QCDR), we would score all the options and use the highest performance score for the eligible clinician or group as described in section II.E.6.a.(1)(b). However, we encourage eligible clinicians to report data for a given performance category using a single submission mechanism.

Finally, section 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs under section 1848(m)(3)(E) of the Act in carrying out MIPS. Section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary, under the CPS methodology, to encourage MIPS eligible clinicians to report on applicable measures with respect to the quality performance category through the use of CEHRT and QCDRs. We note that this proposed rule uses the term CEHRT and certified health IT in different contexts. For an explanation of these terms and contextual use within this proposed rule, we refer readers to section II.E.5.g. of this proposed rule.

We have multiple policies to encourage the usage of QCDRs and CEHRT. In part, we are promoting the use of CEHRT by awarding bonus points in the quality scoring section for measures gathered and reported electronically via the QCDR, qualified registry, Web Interface, or CEHRT submission mechanisms (see II.E.6.b). By promoting use of CEHRT through various submission mechanisms, we believe MIPS eligible clinicians have flexibility in implementing electronic measure reporting in a manner which best suits their practice.

To encourage the use of QCDRs, we have created opportunities for QCDRs to report new and innovative quality measures. In addition, several CPIAs emphasize QCDR participation. Finally, we allow for QCDRs to report data on all MIPS performance categories that require data submission and hope this will become a viable option for MIPS eligible clinicians. We believe these flexible options will allow MIPS eligible clinicians to more easily meet the submission criteria for MIPS, which in turn will positively affect their CPS.

We request comments on these proposals.

(3) Submission Deadlines

For the submission mechanisms described in section II.E.5.a.(2) of this proposed rule, we propose a submission deadline whereby all associated data for all performance categories must be submitted. In establishing the submission deadlines, we have taken into account multiple considerations, including the type of submission mechanism, the MIPS performance period, and stakeholder input and our experiences under the submission deadlines for the PQRS, VM, and Medicare EHR Incentive Programs.

Historically, under the PQRS, VM or Medicare EHR Incentive Programs, the submission of data occurred after the close of the performance periods. Our experience has shown that allowing for the submission of data after the close of the performance period provides either the eligible clinician or the third party intermediary time to ensure the data they submit to us is valid, accurate and has undergone necessary data quality checks. Stakeholders have also stated that they would appreciate the ability to submit data to us on a more frequent basis so they can receive feedback more frequently throughout the performance period. We also note that, as described in section II.E.4. of this proposed rule, the MIPS performance period for payments adjusted in 2019 is calendar year 2017 (January 1 through December 31).

Based on the factors noted, we propose at § 414.1325(e) the data submission deadline for the qualified registry, QCDR, EHR, and attestation submission mechanisms would be March 31 following the close of the performance period. We anticipate that the submission period would begin January 2 following the close of the performance period. For example, for the first MIPS performance period, the data submission period would occur from January 2, 2018, through March 31, 2018. We note that this submission period is the same time frame as what is currently available to eligible professionals and group practices under PQRS. We are interested in receiving feedback on whether it is advantageous to either (1) have a shorter time frame following the close of the performance period, or (2) have a submission period that would occur throughout the performance period, such as bi-annual or quarterly submissions; and (3) whether January 1 should also be included in the submission period. We welcome comments on these items.

We further propose that for the Medicare Part B claims submission mechanism, the submission deadline would occur during the performance period with claims required to be processed no later than 90 days following the close of the performance period. Lastly, for the CMS Web Interface submission mechanism, the submission deadline will occur during an eight-week period following the close of the performance period that will begin no earlier than January 1 and end no later than March 31. For example, the CMS Web Interface submission period could span an 8 week timeframe beginning January 16 and ending March 13. The specific deadline during this timeframe will be published on the CMS Web site.

We request comments on these proposals.

b. Quality Performance Category

(1) Background

(a) General Overview and Strategy

The MIPS program is one piece of the broader health care infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety for all Americans. We seek to balance the sometimes competing considerations of the health system and minimize burdens on health care providers given the short timeframe available under the MACRA for implementation. Ultimately, MIPS should, in concert with other provisions of the Act, support health care that is patient-centered, evidence-based, prevention-oriented, outcome driven, efficient, and equitable.

Under MIPS, clinicians are incentivized to engage in improvement measures and activities that have a proven impact on patient health and safety and are relevant to their patient population. We envision a future state where MIPS eligible clinicians will be seamlessly using their certified health IT to leverage advanced clinical quality measurement to manage patient population with the least amount of workflow disruption and reporting burden. Ensuring clinicians are held accountable for patients' transitions across the continuum of care is imperative. For example, when a patient is discharged from an emergency department to a primary care physician office, the emergency department clinicians should have a shared incentive for a seamless transition. Clinicians may also be working with a QCDR to abstract and report quality measures to CMS and commercial payers and to track patients longitudinally over time for quality improvement.

Ideally, clinicians in the MIPS program will have accountability for quality and resource use measures that are related to one another and will be engaged in CPIAs that directly help them improve in both specialty-specific clinical practice and more holistic areas (for example, patient experience, prevention, population health). Finally, MIPS eligible clinicians will be using CEHRT and other tools which leverage interoperable standards for data capture, usage, and exchange in order to facilitate and enhance patient and family engagement, care coordination among diverse care team members, and, in continuous learning and rapid-cycle improvement leveraging advanced quality measurement and safety initiatives.

One of our goals in the MIPS program is to use a patient-centered approach to program development that will lead to better, smarter, and healthier care. Part of that goal includes meaningful measurement which we hope to achieve through:

- Measuring performance on measures that are relevant and meaningful.
- Maximizing the benefits of CEHRT.
- Flexible scoring that recognizes all of a MIPS eligible clinician's efforts above a minimum level of effort and rewards performance that goes above and beyond the norm.
- Measures that are built around real clinical workflows and data captured in the course of patient care activities.
- Measures and scoring that can discern meaningful differences in performance in each performance category and collectively between low and high performers.

(b) The MACRA Requirements

Sections 1848(q)(1)(A)(i) and (ii) of the Act require the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards and, using that methodology, to provide for a CPS for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act requires us to use the quality performance category in determining each MIPS eligible clinician's CPS, and section 1848(q)(2)(B)(i) of the Act describes the measures and activities that must be specified under the quality performance category.

The statute does not specify the number of quality measures on which a MIPS eligible clinician must report, nor does it specify the amount or type of information that a MIPS eligible clinician must report on each quality measure. However, section 1848(q)(2)(C)(i) of the Act requires the Secretary, as feasible, to emphasize the application of outcomes-based measures.

Sections 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs, and section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage the use of CEHRT and QCDRs for reporting measures under the quality performance category under the CPS methodology, but the statute does not limit the Secretary's discretion to establish other reporting mechanisms.

Section 1848(q)(2)(C)(iv) of the Act generally requires the Secretary to give consideration to the circumstances of non-patient-facing MIPS eligible clinicians and allows the Secretary, to the extent feasible and appropriate, to apply alternative measures or activities to such clinicians.

(c) Relationship to the PQRS and VM

Previously, the PQRS, which is a pay-for-reporting program, defined standards for satisfactory reporting and satisfactory participation to earn payment incentives or to avoid a payment adjustment EPs could choose from a number of reporting mechanisms and options. Based on the reporting option, the EP had to report on a certain number of measures for a certain portion of their patients. In addition, the measures had to span a set number of National Quality Strategy (NQS) domains, information related to the NQS can be found at *http://www.ahrq.gov/workingforquality/about.htm*. The VM built its policies off the PQRS criteria for avoiding the PQRS payment adjustment. Groups that did not meet the criteria as a group to avoid the PQRS payment adjustment or groups that did not have at least 50 percent of the EPs that did not meet the criteria as individuals to avoid the PQRS payment adjustment automatically received the maximum negative adjustment established under the VM and are not measured on their quality performance.

MIPS, in contrast to PQRS, is not a pay-for-reporting program, and we propose that it would not have a "satisfactory reporting" requirement. However, in order to develop an appropriate methodology for scoring the quality performance category, we believe that MIPS needs to define the expected data submission criteria and that the measures need to meet a data completeness standard. In this section we propose the minimum data submission criteria and data completeness standard for the MIPS quality performance category for the submission mechanisms that were proposed earlier in section II.E.5.a. The scoring methodology described in section II.E.6. of this proposed rule would adjust the quality performance category scores based on whether or not an individual MIPS eligible clinician or group met these criteria.

In the MIPS and APMs RFI, we requested feedback on numerous provisions related to data submission criteria including: How many measures should be required? Should we maintain the policy that measures cover a specified number of NQS domains? How do we apply the quality performance category to MIPS eligible clinicians that are in specialties that may not have enough measures to meet our defined criteria? Several themes emerged from the comments. Commenters expressed concern that the general PQRS satisfactory reporting requirement to report nine measures across three NQS domains is too high and forces eligible clinicians to report measures that are not relevant to their practices. The commenters requested a more meaningful set of requirements that focused on patient care, with some expressing the opinion that NQS domain requirements are arbitrary and make reporting more difficult. Some commenters asked that we align measures across payers and consider using core measure sets. Other commenters expressed the need for flexibility and different reporting options for different types of practices.

In response to the comments, and based on our desire to simplify the MIPS reporting system and make the measurement more meaningful, we are proposing MIPS quality criteria that focus on measures that are important to beneficiaries and maintain some of the flexibility from PQRS, while addressing several of the issues that concerned commenters.

- To encourage meaningful measurement, we are proposing to allow individual MIPS eligible clinicians and groups the flexibility to determine the most meaningful measures and reporting mechanisms for their practice.
- To simplify the reporting criteria, we are aligning the submission criteria for several of the reporting mechanisms.
- To reduce administrative burden and focus on measures that matter, we are lowering the expected number of the measures for several of the reporting mechanisms, yet are still requiring that certain types of measures be reported.
- To create alignment with other payers and reduce burden on MIPS eligible clinicians, we are incorporating measures that align with other national payers.
- To create a more comprehensive picture of the practice performance, we are also proposing to use all-payer data where possible.

As beneficiary health is always our top priority, we propose criteria to continue encouraging the reporting of certain measures such as outcome, appropriate use, patient safety, efficiency, care coordination, or patient experience measures. However, we are proposing to remove the requirement for measures to span across multiple domains of the NQS. We continue to believe the NQS domains to be extremely important and we encourage MIPS eligible clinicians to continue to strive to provide care that focuses on: Effective clinical care, communication, efficiency and cost reduction, person and caregiver-centered experience and outcomes, community and population health, and patient safety. While we will not require that a certain number of measures must span multiple domains, we strongly encourage MIPS eligible clinicians to select measures that cross multiple domains. In addition, we believe the MIPS program overall, with the focus on resource use, CPIAs, and advancing care information performance categories will naturally cover many elements in the NQS.

(2) Contribution to Composite Performance Score (CPS)

For the 2019 MIPS adjustment year, the quality performance category will account for 50 percent of the CPS, subject to the Secretary's authority to assign different scoring weights under section 1848(q)(5)(F) of the Act. Section 1848(q)(2)(E)(i)(I)(aa) of the Act states the quality performance category will account for 30 percent of the CPS for MIPS. However, section 1848(q)(2)(E)(i)(I)(bb) of the Act stipulates that for the first and second years for which MIPS applies to payments, the percentage of the CPS applicable for the quality performance category will be increased so that the total percentage points of the increase equals the total number of percentage points by which the percentage applied for the resource use performance category is less than 30 percent. Section 1848(q)(2)(E)(i)(II)(bb) of the Act requires that, for the first year for which MIPS applies to payments, not more than 10 percent of the of CPS shall be based on performance to the resource use performance category. Furthermore, section 1848(q)(2)(E)(i)(II)(bb) of the Act states that, for the second year for which MIPS applies to payments, not more than 15 percent of the CPS shall be based on performance to the resource use performance category. We propose at § 414.1330 for payment years 2019 and 2020, 50 percent and 45 percent, respectively, of the MIPS CPS will be based on performance on the quality performance category. For the third and future years, 30 percent of the MIPS CPS will be based on performance on the quality performance category.

Section 1848(q)(5)(B)(i) of the Act requires the Secretary to treat any MIPS eligible clinician who fails to report on a required measure or activity as achieving the lowest potential score applicable to the measure or activity. Specifically, under our proposed scoring policies, a MIPS eligible clinician or group that reports on all required measures and activities could potentially obtain the highest score possible within the performance category, presuming they performed well on the measures and activities they reported. A MIPS eligible clinician or group who does not meet the reporting threshold would receive a zero score for the unreported items in the category (in accordance with section 1848(q)(5)(B)(i) of the Act). The MIPS eligible clinician or group could still obtain a relatively good score by performing very well on the remaining items, but a zero score would prevent the MIPS eligible clinician or group from obtaining the highest possible score.

(3) Quality Data Submission Criteria

(a) Submission Criteria

The following are the proposed criteria for the various proposed MIPS data submission mechanisms described above in section II.E.5.a. of this proposed rule for the quality performance category.

(i) Submission Criteria for Quality Measures Excluding CMS Web Interface and CAHPS for MIPS

We propose at § 414.1335 that individual MIPS eligible clinicians submitting data via claims and individual MIPS eligible clinicians and groups submitting via all mechanisms (excluding CMS Web Interface, and for CAHPS for MIPS survey, CMS-approved survey vendors) would be required to meet the following submission criteria. We propose that for the applicable 12-month performance period, the MIPS eligible clinician or group would report at least six measures including one cross-cutting measure (if patient-facing) found in Table C and including at least one outcome measure. If an applicable outcome measure is not available, we propose that the MIPS eligible clinician or group would be required to report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. If fewer than six measures apply to the individual MIPS eligible clinician or group, then we propose the MIPS eligible clinician or group would be required to report on each measure that is applicable.

MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS measures in Table A or a set of specialty-specific measure set in Table E. Note that some specialty-specific measure sets include measures grouped by subspecialty; in these cases, the measure set is defined at the subspecialty level.

We designed the specialty-specific measure sets to address feedback we have received in the past that the quality measure selection process can be confusing. A common complaint about PQRS was that EPs were asked to review close to 300 measures to find applicable measures for their specialty. The specialty measure sets in Table E are the same measures that are within Table A, however these are sorted consistent with the American Board of Medical Specialties (ABMS) specialties. Please note that these specialty-specific measure sets are not all inclusive of every specialty or subspecialty. We request comments on the measures proposed under each of the specialty-specific measure sets. Specifically, we seek comments on whether or not the measures proposed for inclusion in the specialty-specific measure sets are appropriate for the designated specialty or sub-specialty and whether there are additional proposed measures that should be included in a particular specialty-specific measure set.

Furthermore, we note that there are some special scenarios for those MIPS eligible clinicians who select their measures from a specialty-specific measure set at either the specialty or subspecialty level (Table E). For example, some of the specialty-specific measure sets have less than six measures, in these instances MIPS eligible clinicians would report on all of the available measures including an outcome measure or, if an outcome measure is unavailable, report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures), within the set and a cross-cutting measure if they are a patient-facing MIPS eligible clinician. To illustrate, the subspecialty-level the electrophysiology cardiac specialist specialty-specific measure set only has three measures within the set, all of which are outcome measures. MIPS eligible clinicians and groups reporting on the electrophysiology cardiac specialist specialty-specific measure set would report on all three measures and since these MIPS eligible clinicians are patient-facing they must also report on a cross-cutting measure which is defined in Table C. In other scenarios, the specialty-specific measure sets may have six or more measures, in these instances MIPS eligible clinicians would report on at least six measures including at least one cross-cutting measure and at least one outcome measure or, if an outcome measure is unavailable, report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measure). Specifically, the general surgery specialty-specific measure set has eight measures within the set, including four outcome measures, three other high priority measures and one process measure. MIPS eligible clinicians and groups reporting on the general surgery specialty-specific measure set would either have the option to report on all measures within the set or could select six measures from the set and since these MIPS eligible clinicians are patient-facing one of their six measures must be a cross-cutting measure which is defined in Table C.

As noted above, the submission criteria for each specialty-specific measure set, or in the measure set defined at the subspecialty level, if applicable. Regardless of the number of measures that are contained in a specialty-specific measure set, MIPS eligible clinicians reporting on a measure set would be required to report at least one cross-cutting measure and either at least one outcome measure or, if no outcome measures are available in that specialty-specific measure set, report another high priority measure. MIPS eligible clinicians or groups that report on a specialty-specific measure set that includes more than six measures can report on as many measures as they wish as long as they meet the minimum requirement to report at least six measures, including one cross-cutting measure and one outcome measure, or if an outcome measure is not available another high priority measure. We seek comment on our proposal to allow reporting of specialty-specific measure sets to meet the submission criteria for the quality performance category, including whether it is appropriate to allow reporting of a measure set at the subspecialty level to meet such criteria, since reporting at the subspecialty level would require reporting on fewer measures. Alternatively, we seek comment on whether we should only consider reporting up to six measures at the higher overall specialty level to satisfy the submission criteria. We note that our proposal to allow reporting of specialty-specific measure sets at the subspecialty level was intended to address the fact that very specialized clinicians who may be represented by our subspecialty categories may only have one or two applicable measures. Further, we note that we will continue to work with specialty societies and other measure developers to increase the availability of applicable measures for specialists across the board.

We propose to define a high priority measure at § 414.1305 as an outcome, appropriate use, patient safety, efficiency, patient experience, or care coordination quality measures. These measures are identified in Table A. We further note that measure types listed as an "intermediate outcome" are considered outcome measures for the purposes of scoring; see section II.E.6.

As an alternative to the above proposals, we also considered requiring individual MIPS eligible clinicians submitting via claims and individual MIPS eligible clinicians and groups submitting via all mechanisms (excluding the CMS Web Interface and, for CAHPS for MIPS survey, CMS-approved survey vendors) to meet the following submission criteria. For the applicable 12-month performance period, the MIPS eligible clinician or group would report at least six measures including one cross-cutting measure (if patient-facing) found in Table C and one high priority measure (outcome, appropriate use, patient safety, efficiency, patient experience, and care coordination measures). If fewer than six measures apply to the individual MIPS eligible clinician or group, then the MIPS eligible clinician or group must report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty-specific measure set in Table E.

As discussed in section II.E.1.b. of this proposed rule, MIPS eligible clinicians who are non-patient-facing MIPS eligible clinicians would not be required to report any cross-cutting measures.

We intend to develop a validation process to review and validate a MIPS eligible clinician's or group's ability to report on at least six quality measures, or a specialty-specific measure set, with a sufficient sample size, including at least one cross-cutting measure (if the MIPS eligible clinician is patient-facing) and either an outcome measure if one is available or another high priority measure. If a MIPS eligible clinician or group had the ability to report on the minimum required measures with sufficient sample size and elects to report on fewer than the minimum required measures, then, as described in the proposed scoring algorithm in section II.E.6., the missing measures would be scored with a zero performance score.

Our proposal is a decrease from the 2016 PQRS requirement to report at least nine measures. In addition, as previously noted, we propose to no longer require reporting across multiple NQS domains. We believe these proposals are the best approach for the quality performance category because it decreases the MIPS eligible clinician's reporting burden while focusing on more meaningful types of measures.

We also note that we believe that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality of care patients receive. To keep the emphasis on such measures in the statute, we plan to increase the requirements for reporting outcome measures over the next several years through future rulemaking, as more outcome measures become available. For example, we may increase the required number of outcome measures to two or three. We also believe that appropriate use, patient experience, safety, and care coordination measures are more relevant than clinical process measures for improving care of patients. Through future rulemaking, we plan to increase the requirements for reporting on these types of measures over time.

In consideration of which MIPS measures to identify as reasonably focused on appropriate use, we have selected measures which focus on minimizing overuse of services, treatments, or the related ancillary testing that may promote overuse of services and treatments. We have also included select measures of underuse of specific treatments or services that either (1) reflected overuse of alternative treatments and services that were are not evidence-based or supported by clinical guidelines; or (2) where the intent of the measure reflected overuse of alternative treatments and services that were not evidence-based or supported by clinical guidelines. We realize there are differing opinions on what constitutes appropriate use. Therefore, we are seeking comments on what specific measures of over or under use should be included as appropriate use measures.

We plan to continue developing care episode groups, patient condition groups, and patient relationship categories (and codes for such groups and categories). We plan to incorporate new measures as they become available and will give the public the opportunity to comment on these provisions through future notice and comment rulemaking. We also will closely examine the recommendations from HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) study, once they are available, on the issue of risk adjustment for socioeconomic status on quality measures and resource use as required by section 2(d) of the IMPACT Act and incorporate them as feasible and appropriate through future rulemaking. In addition, we are seeking comments on ways to minimize potential gaming, for example, requiring MIPS eligible clinicians to report only on measures for which they have a sufficient sample size, to address concerns that MIPS eligible clinicians may solely report on measures that do not have a sufficient sample size to decrease the overall weight on their quality score. More information on the way we propose to score MIPS eligible clinicians in this scenario is in section II.E.6.a.2. We also seek comment on whether these proposals sufficiently encourage providers and measure developers to move away from clinical process measures and towards outcome measures and measures that reflect other NQS domains. We request comments on these proposals.

(ii) Submission Criteria for Quality Measures for Groups Reporting via the CMS Web Interface

We propose at § 414.1335 the following criteria for the submission of data on quality measures by registered groups of 25 or more MIPS eligible clinicians who want to report via the CMS Web Interface. For the applicable 12-month performance period, we propose that the group would be required to report on all measures included in the CMS Web Interface completely, accurately, and timely by populating data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries. A group would be required to report on at least one measure for which there is Medicare patient data. We do not propose any modifications to this reporting process. Groups reporting via the CMS Web Interface are required to report on all of the measures in the set. Any measures not reported would be considered zero performance for that measure in our scoring algorithm.

Lastly, from our experience with using the CMS Web Interface under prior Medicare programs we are aware groups may register for this mechanism and have zero Medicare patients assigned and sampled to them. We clarify that should a group have no assigned patients, then the group, or individual MIPS eligible clinicians within the group, would need to select another mechanism to submit data to MIPS. If a group does not typically see Medicare patients for which the CMS Web Interface measures are applicable, or if the group does not have adequate billing history for Medicare patients to be used for assignment and sampling of Medicare patients into the CMS Web Interface, we advise the group to participate in the MIPS via another reporting mechanism.

As discussed in the CY 2016 PFS final rule with comment period (80 FR 71144), beginning with the 2017 PQRS payment adjustment, the PQRS aligned with the VM's beneficiary attribution methodology for purposes of assigning patients for groups that registered to participate in the PQRS Group Reporting Option (GPRO) using the CMS Web Interface (formerly referred to as the GPRO Web Interface). For certain quality and cost measures, the VM uses a two-step attribution process to associate beneficiaries with TINs during the period in which performance is assessed. This process attributes a beneficiary to the TIN that bills the plurality of primary care services for that beneficiary (79 FR 67960–67964). We propose to continue to align the 2019 CMS Web Interface beneficiary assignment methodology with the measures that used to be in the VM: the population quality measures discussed below in this proposed rule and total per capita cost for all attributed beneficiaries discussed in section II.E.5.e. of this proposed rule. As MIPS is a different program, we propose to modify the attribution process to update the definition of primary care services and to adapt the attribution to different identifiers used in MIPS. These changes are discussed in section II.E.5.e. of this proposed rule. We request comments on these proposals.

(iii) Performance Criteria for Quality Measures for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

The CAHPS for MIPS survey (formerly known as the CAHPS for PQRS survey) consists of the core CAHPS Clinician & Group Survey developed by AHRQ, plus additional survey questions to meet CMS's information and program needs. For more information on the CAHPS for MIPS survey, please see the explanation of the CAHPS for PQRS survey in the CY 2016 PFS final rule with comment period (80 FR 71142 through 71143). While we anticipate that the CAHPS for MIPS survey will closely align with the CAHPS for PQRS survey, we may explore the possibility of updating the CAHPS for MIPS survey under MIPS, specifically we may not finalize all proposed Summary Survey Measures (SSM).

We propose to allow registered groups of two or more MIPS eligible clinicians to voluntarily elect to participate in the CAHPS for MIPS survey. Specifically, we propose at § 414.1335 the following criteria for the submission of data on the CAHPS for MIPS survey by registered groups via CMS-approved survey vendor: For the applicable 12-month performance period, the group must have the CAHPS for MIPS survey reported on its behalf by a CMS-approved survey vendor. In addition, the group will need to use another submission mechanism (that is, qualified registries, QCDRs, EHR etc.) to complete their quality data submission. The CAHPS for MIPS survey would count as one cross-cutting and/or a patient experience measure, and the group would be required to submit at least five other measures through one other data submission mechanisms. A group may report any five measures within MIPS plus the CAHPS for MIPS survey to achieve the six measures threshold.

The administration of the CAHPS for MIPS survey would contain a six-month look-back period. In previous years the CAHPS for PQRS survey was administered from November to February of the reporting year. We propose to retain the same survey administration period for the CAHPS for MIPS survey. Groups that voluntarily elect to participate in the CAHPS for MIPS survey would bear the cost of contracting with a CMS-approved survey vendor to administer the CAHPS for MIPS survey on the group's behalf, just as groups do now for the CAHPS for PQRS survey.

Under current provisions of PQRS, the CAHPS for PQRS survey is required for groups of 100 or more eligible clinicians. Although we are not requiring groups to participate in the CAHPS for MIPS survey, we do still believe patient experience is important and we are therefore proposing a scoring incentive for those groups who report via the CAHPS for MIPS survey. As described in section II.E.3.d. of this proposed rule, we propose that groups electing to report the CAHPS for MIPS survey, would be required to register for the reporting of data. Because we believe patients' experiences as they interact with the health care system is important, our proposed scoring methodology would give bonus points for reporting CAHPS data (or other patient experience measures). Please refer to section II.E.6. for further details. We are interested in receiving comments on whether the CAHPS for MIPS survey should be required for groups of 100 or more MIPS eligible clinicians or whether it should be voluntary.

Currently, the CAHPS for PQRS beneficiary sample is based on Medicare claims data. Therefore, only Medicare beneficiaries can be selected to participate in the CAHPS for PQRS survey. In future years of the MIPS program, we may consider expanding the potential patient experience measures to all payers, so that Medicare and non-Medicare patients can be included in the CAHPS for MIPS survey sample. We are seeking comments on criteria that would ensure comparable samples. We seek comments on these proposals.

(b) Data Completeness Criteria

We want to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance. Section 1848(q)(5)(H) of the Act provides that analysis of the quality performance category may include quality measure data from other payers, specifically, data submitted by MIPS eligible clinicians with respect to items and services furnished to individuals who are not individuals entitled to benefits under Part A or enrolled under Part B of Medicare.

To ensure completeness for the broadest group of patients, we propose at § 414.1340 the criteria below. MIPS eligible clinicians and groups who do not meet the proposed reporting criteria noted below would fail the quality component of MIPS.

- Individual MIPS eligible clinicians or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR need to report on at least 90 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the performance period. In other words, for these submission mechanisms, we would expect to receive quality data for both Medicare and non-Medicare patients.
- Individual MIPS eligible clinicians submitting data on quality measures data using Medicare Part B claims, would report on at least 80 percent of the Medicare Part B patients seen during the performance period to which the measure applies.
- Groups submitting quality measures data using the CMS Web Interface or a CMS-approved survey vendor to report the CAHPS for MIPS survey would need to meet the data submission requirements on the sample of the Medicare Part B patients CMS provides.

We propose to include all-payer data for the QCDR, qualified registry, and EHR submission mechanisms because we believe this approach provides a more complete picture of each MIPS eligible clinicians scope of practice and provides more access to data about specialties and subspecialties not currently captured in PQRS. In addition, we propose the QCDR, qualified registry, or EHR submission must contain a minimum of one quality measure for at least one Medicare patient.

We desire all-payer data for all reporting mechanisms, yet certain reporting mechanisms are limited to Medicare Part B data. Specifically, the claims reporting mechanism relies on individual MIPS eligible clinicians attaching quality information on Medicare Part B claims; therefore only Medicare Part B patients can be reported by this mechanism. The CMS Web

Interface and the CAHPS for MIPS survey currently rely on sampling protocols based on Medicare Part B billing; therefore, only Medicare Part B beneficiaries are sampled through that methodology. We welcome comments on ways to modify the methodology to assign and sample patients for these mechanisms using data from other payers.

The data completeness criteria we are proposing are an increase in the percentage of patients to be reported by each of the mechanisms when compared to PQRS. We believe the proposed thresholds are appropriate to ensure a more accurate assessment of a MIPS eligible clinician's performance on the quality measures and to avoid any selection bias that may exist under the current PQRS requirements. In addition, we would like to align all the reporting mechanisms as closely as possible with achievable data completeness criteria. We intend to continually assess the proposed data completeness criteria and will consider increasing these thresholds for future years of the program. We request comments on this proposal.

We are also interested in data that would indicate these data completeness criteria are inappropriate. For example, we could envision that reporting a cross-cutting measure would not always be appropriate for every telehealth service or for certain acute situations. We would not want a MIPS eligible clinician to fail reporting the measure in appropriate circumstances; therefore, we seek feedback data and circumstances where it would be appropriate to lower the data completeness criteria.

(c) Summary of Data Submission Criteria Proposals

Table 3 reflects our proposed Quality Data Submission Criteria for MIPS:

TABLE 3: Summary of Proposed Quality Data Submission Criteria for MIPS via Part B Claims, QCDR, Qualified Registry, EHR, CMS Web Interface, and CAHPS for MIPS Survey

Performance Period	Measure Type	Submission Mechanism	Submission Criteria	Data Completeness
Jan 1 – Dec 31	Individual MIPS eligible clinicians	Part B Claims	Report at least six measures including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.	80 percent of MIPS eligible clinician's patients
Jan 1 – Dec 31	Individual MIPS eligible clinicians or Groups	QCDR Qualified Registry EHR	Report at least six measures including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.	90 percent of MIPS eligible clinician's or groups patients
Jan 1 – Dec 31	Groups	CMS Web Interface	Report on all measures included in the CMS Web Interface; AND populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned	Sampling requirements for their Medicare Part B patients

Performance Period	Measure Type	Submission Mechanism	Submission Criteria	Data Completeness
			beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.	
Jan 1 – Dec 31	Groups	CAHPS for MIPS Survey	CMS-approved survey vendor would have to be paired with another reporting mechanism to ensure the minimum number of measures are reported. CAHPS for MIPS Survey would fulfill the requirement for one cross-cutting and/or a patient experience measure towards the MIPS quality data submission criteria. CAHPS for MIPS Survey will only count for one measure.	Sampling requirements for their Medicare Part B patients

(4) Application of Quality Measures to Non-Patient-Facing MIPS Eligible Clinicians

Section 1848(q)(2)(C)(iv) of the Act provides that the Secretary must give consideration to the circumstances of non-patient-facing MIPS eligible clinicians and may, to the extent feasible and appropriate, take those circumstances into account and apply alternative measures or activities that fulfill the goals of the applicable performance category to such clinicians. In doing so, the Secretary must consult with non-patient-facing MIPS eligible clinicians.

In addition, section 1848(q)(5)(F) to the Act allows the Secretary to re-weight MIPS performance categories if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician. We assume many non-patient-facing MIPS eligible clinician will not have sufficient measures and activities applicable and available to report and will not be scored on the quality performance category under MIPS. We refer readers to section II.E.6. of this proposed rule to discuss how we address performance categories weighting for MIPS eligible clinicians for whom no measures exist in a given category.

In the MIPS and APMs RFI, we solicited feedback on how we should apply the four MIPS performance categories to non-patient-facing MIPS eligible clinicians and what types of measures and/or CPIAs (new or from other payments systems) would be appropriate for these MIPS eligible clinicians. We also engaged with seven separate organizations representing non-patient-facing MIPS eligible clinicians in the areas of anesthesiology, radiology/imaging, pathology, and nuclear medicine, specifically cardiology. Organizations we spoke with representing several specialty areas indicated that Appropriate Use Criteria (AUC) can be incorporated into the CPIA performance category by including activities related to appropriate assessments and reducing unnecessary tests and procedures. AUC are distinct from clinical guidelines and specify when it is appropriate to use a diagnostic test or procedure—thus reducing unnecessary tests and procedures. Use of AUC is an important CPIA as it fosters appropriate utilization and is increasingly used to improve quality in cardiovascular medicine, radiology, imaging, and pathology. These groups also highlighted that many non-patient-facing MIPS eligible clinicians have multiple patient safety and practice assessment measures and activities that could be included, such as activities that are tied to their participation in the Maintenance of Certification (MOC) Part IV for improving the clinician's practice. One organization expressed concern that because their quality measures are specialized, some members could be negatively affected when comparing quality scores because they did not have the option to be compared on a broader, more common set of measures. The MIPS and APMs RFI commenters noted that the emphasis should be on measures and activities that are practical, attainable, and meaningful to individual circumstances and that measurement should be as outcomes-based to the extent possible. The MIPS and APMs RFI commenters emphasized that CPIAs should be selected from a very broad array of choices and that ideally non-patient-facing MIPS eligible clinicians should help develop those activities so that they provide value and are easy to document. For more details regarding the CPIA performance category refer to section II.E.5.f. of this proposed rule. The comments from these organizations were considered in developing these proposals.

We understand that non-patient-facing MIPS eligible clinicians may have a limited number of measures on which to report. Therefore, we propose at § 414.1335 that non-patient-facing MIPS eligible clinicians would be required to meet the otherwise applicable submission criteria, but would not be required to report a cross-cutting measure.

Thus we would employ the following strategy for the quality performance criteria to accommodate non-patient-facing MIPS eligible clinicians:

- Allow non-patient-facing MIPS eligible clinicians to report on specialty-specific measure set (which may have fewer than the required six measures).

- Allow non-patient-facing MIPS eligible clinicians to report through a QCDR that can report non-MIPS measures.
- Non-patient-facing MIPS eligible clinicians would be exempt from reporting a cross-cutting measure as proposed at § 414.1340.

We request comments on these proposals.

(5) Application of Additional System Measures

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures used for inpatient hospitals, for purposes of the quality and resource use performance categories. The Secretary may not, however, use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

In the MIPS and APMs RFI, we sought comment on how we could best use this authority. Some facility-based commenters requested a submission option that allows the MIPS eligible clinician to be scored based on the facility's measures. These commenters noted that the care they provide directly relates to and affects the facility's overall performance on quality measures and that using this score may be a more accurate reflection of the quality of care they provide than the quality measures in the PQRS or the VM program.

We will consider an option for facility-based MIPS eligible clinicians to elect to use their institution's performance rates as a proxy for the MIPS eligible clinician's quality score. We are not proposing an option for year 1 of MIPS because there are several operational considerations that must be addressed before this option can be implemented. We are requesting comment on the following issues: (1) Whether we should attribute a facility's performance to a MIPS eligible clinician for purposes of the quality and resource use performance categories and under what conditions such attribution would be appropriate and representative of the MIPS eligible clinician's performance; (2) possible criteria for attributing a facility's performance to a MIPS eligible clinician for purposes of the quality and resource use performance categories; and (3) the specific measures and settings for which we can use the facility's quality and resource use data as a proxy for the MIPS eligible clinician's quality and resource use performance categories; and (4) if attribution should be automatic or if a MIPS eligible clinician or group should elect for it to be done and choose the facilities through a registration process. We may also consider other options that would allow us to gain experience. We seek comments on these approaches.

(6) Global and Population-Based Measures

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the quality performance category.

Under the current PQRS program and Medicare EHR Incentive Program quality measures are categorized by domains which include global and population-based measures. We identified population and community health measures as one of the quality domains related to the CMS Quality Strategy and the NQS priorities for health care quality improvement discussed in section II.E.5.c. of this proposed rule. Population-based measures are also used in the Medicare Shared Savings Program and for groups in the VM. For example, in 2015, clinicians were held accountable for a component of the Agency for Health Care Research (AHRQ) population-based, Ambulatory Care Sensitive Condition measures as part of a larger set of Prevention Quality Indicators (PQIs). Two broader composite measures of acute and chronic conditions are calculated using the respective individual measure rates for VM calculations. These PQIs assess the quality of the health care system as a whole, and especially the quality of ambulatory care, in preventing medical complications that lead to hospital admissions.

In the CY 2015 PFS final rule with comment period (79 FR 67909), Medicare Payment Advisory Commission (MedPAC) commented that we should move quality measurement for ACOs, Medicare Advantage (MA) plans, and FFS Medicare in the direction of a small set of population-based outcome measures, such as potentially preventable inpatient hospital admissions, emergency department visits, and readmissions. In the June 2014 MedPAC Report to the Congress: *Medicare and the Health Care Delivery System* MedPAC suggests considering an alternative quality measurement approach that would use population-based outcome measures to publicly report on quality of care across Medicare's three payment models, FFS, Medicare Advantage, and ACOs.

In creating policy for global and population-based measures for MIPS we considered a more broad-based approach to the use of "global" and "population-based" measures in the MIPS quality performance category. After considering the above we propose to use the acute and chronic composite measures of Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicators (PQIs) that meet a minimum sample size in the calculation of the quality measure domain for the MIPS total performance score; see Table B. Eligible clinicians will be evaluated on their performance on these measures in addition to the six required quality measures discussed previously and summarized in Table A. Based on experience in the VM program, these measures have been determined to be reliable with a minimum case size of 20. Average reliabilities for the acute and chronic measures range from 0.64 to 0.79 for groups and individual MIPS eligible clinicians. We intend to incorporate a clinical risk adjustment as soon as feasible to the PQI composites and continue to research ways to develop and use other population-based measures for the MIPS program that could be applied to greater numbers of MIPS eligible clinicians going forward. In addition to the acute and chronic composite measure, we also propose to include the all-cause hospital readmissions measure from the VM as we believe this measure also encourages care coordination. In the CY 2016 Medicare PFS final rule (80 FR 71296), we did a reliability analysis that indicates this measure is not reliable for solo clinicians or practices with fewer than 10 clinicians; therefore, we propose to limit this measure to groups with 10 or more clinicians and to maintain the current VM requirement of 200 cases. Eligible clinicians in groups with 10 or more clinicians with sufficient cases will be evaluated on their performance on this measure in addition to the six required quality measures discussed previously and summarized in Table A.

Furthermore, the proposed claims-based population measures would rely on the same two-step attribution methodology that is currently used in the VM (79 FR 67961 through 67694). The attribution focuses on the delivery of primary care services (77 FR 69320) by both primary care physicians and specialists. This attribution logic aligns with the total per capita measure and is similar to, but not exactly the same, as the assignment methodology used for the Shared Savings Program. For example, the Shared Savings Program definition of primary care services can be found at § 425.20 and excludes claims for certain Skilled Nursing Facility (SNF) services that include the POS 31 modifier). In section II.E.5.e.3.a.i. of this proposed rule, we propose to exclude the POS 31 modifier from the definition of primary care services. As described in section II.E.2. of this proposed rule, the attribution would be modified slightly to account for the MIPS eligible clinician identifiers. We are seeking comments on additional measures or measure topics for future years of MIPS and attribution methodology. We request comments on these proposals.

c. Selection of Quality Measures for Individual MIPS Eligible Clinicians and Groups

(1) Annual List of Quality Measures Available for MIPS Assessment

Under section 1848(q)(2)(D)(i) of the Act, the Secretary, through notice and comment rulemaking, must establish an annual list of quality measures from which MIPS eligible clinicians may choose for purposes of assessment for a performance period. The annual list of quality measures must be published in the **Federal Register** no later than November 1 of the year prior to the first day of a performance period. Updates to the annual list of quality measures must be published in the **Federal Register** not later than November 1 of the year prior to the first day of each subsequent performance period. Updates may include the removal of quality measures, the addition of new quality measures, and the inclusion of existing quality measures that the Secretary determines have undergone substantive changes. For example, a quality measure may be considered for removal if the Secretary determines that the measure is no longer meaningful, such as measures that are topped out. A measure may be considered topped out if measure performance is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made. Additionally, we are not the measure steward for most of the proposed quality measures available for inclusion in the MIPS annual list of quality measures. We rely on outside measure stewards and developers to maintain these measures. Therefore, we also propose to give consideration in removing measures that measure stewards are no longer able to maintain.

Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a "Call for Quality Measures" each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of quality measures, as well as updates to the measures. Although we will accept quality measures submissions at any time, only measures submitted before June 1 of each year will be considered for inclusion in the annual list of quality measures for the performance period beginning 2 years after the measure is submitted. For example, a measure submitted prior to June 1, 2016 would be considered for the 2018 performance period. Of those quality measures submitted before June 1, we will determine which quality measures will move forward as potential measures for use in MIPS. Prior to finalizing new measures for inclusion in the MIPS program, those measures that we determine will move forward must also go through notice-and-comment rulemaking and the new proposed measures must be submitted to a peer review journal. Finally, for quality measures that have undergone substantive changes, we propose to identify measures including but not limited to measures that have had measure specification, measure title, and domain changes. Through NQF's or the measure steward's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the intent of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures.

In the first year of MIPS, we propose to maintain a majority of previously implemented measures in PQRS (80 FR 70885–71386) for inclusion in the annual list of quality measures. These measures can be found in the appendix at Table A: Proposed Individual Quality Measures Available for MIPS Reporting in 2017. Also included in the appendix in Table B is a list of quality measures that do not require data submission, some of which were previously implemented in the VM (80 FR 71273–71300), that we propose to include in the annual list of MIPS quality measures. These measures can be calculated from administrative claims data and do not require data submission. We are also proposing measures that were not previously finalized for implementation in the PQRS program. These measures and their draft specifications are listed in Table D. The proposed specialty-specific measure sets are listed in Table E. As we continue to develop measures and specialty-specific measure sets, we recognize that there are many MIPS eligible clinicians who see both Medicaid and Medicare patients and seek to align our measures to utilize Medicaid measures in the MIPS quality performance category. We believe that aligning Medicaid and Medicare measures is in the interest of all providers and will help drive quality improvement for our beneficiaries. For future years, we seek comment about the addition of a "Medicaid measure set" based on the CMCS Adult Core Set (*https://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/adult-health-care-quality-measures.html*). Measures we are proposing for removal can be found in Table F and measures that will have substantive changes for the 2017 performance period can be found in Table G. In future years, the annual list of quality measures available for MIPS assessment will occur through rulemaking. We request comment on these proposals. In particular, we seek comment on whether there are any measures that commenters believe should be classified in a different NQS domain than what was proposed or that should be classified as a different measure type (*e.g.*, process vs. outcome) than what was proposed.

(2) Call for Quality Measures

Each year, we have historically solicited a "Call for Quality Measures" from the public for possible quality measures for consideration for the PQRS. Under MIPS, we propose to continue the annual "Call for Quality Measures" as a way to engage eligible clinician organizations and other relevant stakeholders in the identification and submission of quality measures for consideration. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards. However, we do not believe there needs to be any special restrictions on the type or make-up of the organizations carrying out the process of development of quality measures. Any such restriction would limit the development of quality measures and the scope and utility of the quality measures that may be considered for endorsement. Submission of potential quality measures regardless of whether they were previously published in a proposed rule or endorsed by an entity with a contract under section 1890(a) of the Act, which is currently the National Quality Forum, is encouraged.

As previously noted, we encourage the submission of potential quality measures regardless of whether such measures were previously published in a proposed rule or endorsed by an entity with a contract under section 1890(a) of the Act. However, consistent with the expectations established under PQRS, we propose to request that stakeholders apply the following considerations when submitting quality measures for possible inclusion in MIPS:

- Measures that are not duplicative of an existing or proposed measure.
- Measures that are beyond the measure concept phase of development and have started testing, at a minimum.
- Measures that include a data submission method beyond claims-based data submission.
- Measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address a performance gap or measurement gap.

We request comment on these proposals.

(3) Requirements

Section 1848(q)(2)(D)(iii) of the Act provides that, in selecting quality measures for inclusion in the annual final list of quality measures, the Secretary must provide that, to the extent practicable, all quality domains (as defined in section 1848(s)(1)(B) of the Act) are addressed by such measures and must ensure that the measures are selected consistent with the process for selection of measures under section 1848(k), (m), and (p)(2) of the Act.

Section 1848(s)(1)(B) of the Act defines "quality domains" as at least the following domains: clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention. We believe the five domains applicable to the quality measures under MIPS are included in the NQS's six priorities as follows:

- *Patient Safety.* These are measures that reflect the safe delivery of clinical services in all health care settings. These measures may address a structure or process that is designed to reduce risk in the delivery of health care or measure the occurrence of an untoward outcome such as adverse events and complications of procedures or other interventions. We believe this NQS priority corresponds to the domain of safety.
- *Person and Caregiver-Centered Experience and Outcomes.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level. These are measures of organizational structures or processes that foster both the inclusion of persons and family members as active members of the health care team and collaborative partnerships with health care providers and provider organizations or can be measures of patient-reported experiences and outcomes that reflect greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management. We believe this NQS priority corresponds to the domain of patient and caregiver experience.
- *Communication and Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication. They may also be measures that reflect outcomes of successful coordination of care. We believe this NQS priority corresponds to the domain of care coordination.
- *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines or measures of patient-centered outcomes of disease states. We believe this NQS priority corresponds to the domain of clinical care.
- *Community/Population Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. They may be measures of processes focused on primary prevention of disease or general screening for early detection of disease unrelated to a current or prior condition. We believe this NQS priority corresponds to the domain of population health and prevention.
- *Efficiency and Cost Reduction.* These are measures that reflect efforts to lower costs and to significantly improve outcomes and reduce errors. These are measures of cost, resource use and appropriate use of health care resources or inefficiencies in health care delivery.

Section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures. Although not required to go through the pre-rulemaking process, we have found the NQF convened Measure Application Partnership's (MAP) input valuable. We propose that we may consider the MAP's recommendations as part of the comprehensive assessment of each measure considered for inclusion under MIPS. Elements we propose to consider in addition to those listed in the "Call for Quality Measures" section of this rule include a measure's fit within MIPS, if a measure fills clinical gaps, changes or updates to performance guidelines, and other program needs. Further, we will continue to explore how global and population-based measures can be expanded and plan to add additional population-based measures through future rulemaking. We request comment on these proposals.

(4) Peer Review

Section 1848(q)(2)(D)(iv) of the Act, requires the Secretary to submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals before including such measures in the final annual list of quality measures. The submission must include the method for developing and selecting such measures, including clinical and other data supporting such measures. We believe this opportunity for peer review helps ensure that new measures published in the final rule are meaningful and comprehensive. We propose to use the Call for Quality Measures process as an opportunity to gather the information necessary to draft the journal articles for submission from measure developers, measure owners and measure stewards since CMS does not always develop measures for the quality programs. Information from measure developers, measure owners and measure stewards will include but is not limited to: Background, clinical evidence and data that supports the intent of the measure; recommendation for the measure that may come from a study or the United States Preventive Task Force (USPTF) recommendations; and how this measure would align with the CMS Quality Strategy. The Call for Quality Measures is a yearlong process; however, to be aligned with the regulatory process, establishing the proposed measure set for the year generally begins in April and concludes in July. We will submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals before including such measures in the final annual list of quality measures. We request comment on this proposal. Additionally, we seek comment on mechanisms that could be used, such as the CMS Web site, to notify the public that the requirement to submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals is met. Additionally, we seek comment on the type of information that should be included in such notification.

(5) Measures for Inclusion

Under section 1848(q)(2)(D)(v) of the Act, the final annual list of quality measures must include, as applicable, measures from under section 1848(k), (m), and (p)(2) of the Act, including quality measures among: (1) Measures endorsed by a consensus-based entity; (2) measures developed under section 1848(s) of the Act; and (3) measures submitted in response to the "Call for Quality Measures" required under section 1848(q)(2)(D)(ii) of the Act. Any measure selected for inclusion that is not endorsed by a consensus-based entity must have an evidence-based focus. Further, under section 1848(q)(2)(D)(ix), the process under section 1890A of the Act is considered optional.

Section 1848(s)(1) of the Act, as added by section 102 of the MACRA, also requires the Secretary of Health and Human Services to develop a draft plan for the development of quality measures by January 1, 2016. We solicited comments from the public on the "Draft CMS Measure Development Plan" through March 1, 2016. The final CMS Measure Development Plan must be finalized and posted on the CMS Web site by May 1, 2016.

(6) Exception for QCDR Measures

Section 1848(q)(2)(D)(vi) of the Act provides that quality measures used by a QCDR under section 1848(m)(3)(E) of the Act are not required to be established through notice-and-comment rulemaking or published in the **Federal Register**; be submitted for publication in applicable specialty-appropriate, peer-reviewed journals, or meet the criteria described in section 1848(q)(2)(D)(v) of the Act. The Secretary must publish the list of quality measures used by such QCDRs on the CMS Web site. We propose to post the quality measures for use by qualified clinical data registries in the spring of 2017 for the initial performance period and no later than January 1 for future performance periods.

Quality measures that are owned or developed by the QCDR entity and proposed by the QCDR for inclusion in MIPS but are not a part of the MIPS quality measure set are considered non-MIPS measures. If a QCDR wants to use a non-MIPS measure for inclusion in the MIPS program for reporting, we propose that these measures go through a rigorous CMS approval process during the QCDR self-nomination period. Specific details on third party entity requirements can be found in section II.E.9 of this proposed rule. The measure specifications will be reviewed and each measure will be analyzed for its scientific rigor, technical feasibility, duplication to current MIPS measures, clinical performance gaps, as evidenced by background and/or literature review, and relevance to specialty practice quality improvement. Once the measures are analyzed, the QCDR will be notified of which measures are approved for implementation. Each non-MIPS measure will be assigned a unique ID that can only be used by the QCDR that proposed it. Although non-MIPS measures are not required to be NQF-endorsed, we encourage the use of NQF-endorsed measures and measures that have been in use prior to implementation in MIPS. Lastly, we note that MIPS eligible clinicians reporting via QCDR have the option of reporting MIPS measures included in Table A in the Appendix to the extent that such measures are appropriate for the specific QCDR and have been approved by CMS. We request comment on these proposals.

(7) Exception for Existing Quality Measures

Section 1848(q)(2)(D)(vii)(II) of the Act provides that any quality measure specified by the Secretary under section 1848(k) or (m) of the Act and any measure of quality of care established under section 1848(p)(2) of the Act for a performance or reporting period beginning before the first MIPS performance period (herein referred to collectively as "existing quality measures") must be included in the annual list of MIPS quality measures unless removed by the Secretary. As discussed in section II.E.4 of this proposed rule, we are proposing that the performance period for the 2019 MIPS adjustment would be CY 2017, that is, January 1, 2017 through December 31, 2017. Therefore existing quality measures would consist of those that have been specified or established by the Secretary as part of the PQRS measure set or VM measure set for a performance or reporting period beginning before CY 2017.

Section 1848(q)(2)(D)(vii)(I) of the Act provides that existing quality measures are not required to be established through notice-and-comment rulemaking or published in the **Federal Register** (although they remain subject to the applicable requirements for removing measures and including measures that have undergone substantive changes), nor are existing quality measures required to be submitted for publication in applicable specialty-appropriate, peer-reviewed journals.

(8) Consultation With Relevant Eligible Clinician Organizations and Other Relevant Stakeholders

Section 1890A of the Act, as added by section 3014(b) of the ACA, requires that the Secretary establish a pre-rulemaking process under which certain steps occur for the selection of certain categories of quality and efficiency measures, one of which is that the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) convenes multi-stakeholder groups to provide input to the Secretary on the selection of such measures. These categories are described in section 1890(b)(7)(B) of the Act and include the quality measures selected for the PQRS. In accordance with section 1890A(a)(1) of the Act, the NQF convened multi-stakeholder groups by creating the MAP. Section 1890A(a)(2) of the Act requires that the Secretary make publicly available by December 1 of each year a list of the quality and efficiency measures that the Secretary is considering under Medicare. The NQF must provide the Secretary with the MAP's input on the selection of measures by February 1 of each year. The lists of measures under consideration for selection are available at *http://www.qualityforum.org/map/*.

Section 1848(q)(2)(D)(viii) of the Act provides that relevant eligible clinician organizations and other relevant stakeholders, including state and national medical societies, must be consulted in carrying out the annual list of quality measures available for MIPS assessment. Section 1848(q)(2)(D)(ii)(II) of the Act defines an eligible clinician organization as a professional organization as defined by nationally recognized specialty boards of certification or equivalent certification boards. Section 1848(q)(2)(D)(viii) of the Act further provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures.

Although MIPS quality measures are not required to go through the pre-rulemaking process under section 1890A of the Act, we have found the MAP's input valuable. The MAP process enables us to consult with relevant eligible professional organizations and other stakeholders, including state and national medical societies in finalizing the annual list of quality measures. In addition to the MAP's input this year, we also received input from the Core Measure Collaborative, specifically the America's Health Insurance Plans (AHIP), on core quality measure sets. The Core Measure Collaborative was organized by CMS in coordination with AHIP in 2014. This stakeholder workgroup has developed several condition-specific core measure sets to help align reporting requirements for private and public health insurance providers. Sixteen of the newly proposed measures under MIPS were recommended by the Core Measure Collaborative.

(9) Cross-Cutting Measures for 2017 and Beyond

Under PQRS we realized the value in requiring EPs to report a cross-cutting measure and have proposed to continue the use of cross-cutting measures under MIPS. The cross-cutting measures help focus our efforts on population health improvement and they also allow for meaningful comparisons between MIPS eligible clinicians. Under MIPS, we are proposing fewer cross-cutting measures than those available under PQRS for 2016 reporting; however, we believe the list contains measures for which all patient-facing MIPS eligible clinicians should be able to report, as the measures proposed include commonplace health improvement activities such as checking blood pressure and medication management. We have eliminated some measures for which the reporting MIPS eligible clinician may not actually be providing the care, but are just reporting another MIPS eligible clinician's performance result. An example of this would be a MIPS eligible clinician who never manages a diabetic patient's glucose, yet previously could have reported a measure about hemoglobin A1c based on an encounter. This type of reporting will likely not help improve or confirm the quality of care the MIPS eligible clinician provides to his or her patients. Although there are fewer proposed cross-cutting measures under MIPS, in previous years some measures were too specialized and could not be reported on by all MIPS eligible clinicians. The proposed cross-cutting measures under MIPS are more broadly applicable and can be reported on by most specialties. The proposed MIPS cross-cutting measure set will be available on the CMS Web site. Non-patient-facing MIPS eligible clinicians do not have a cross-cutting measure requirement. The cross-cutting measures that were available under PQRS for 2016 reporting that are not being proposed as cross-cutting measures for 2017 reporting are:

- PQRS #001 (Diabetes: Hemoglobin A1c Poor Control).
- PQRS #046 (Medication Reconciliation Post Discharge).
- PQRS #110 (Preventive Care and Screening: Influenza Immunization).
- PQRS #111 (Pneumonia Vaccination Status for Older Adults).
- PQRS #112 (Breast Cancer Screening).
- PQRS #131 (Pain Assessment and Follow-Up).
- PQRS #134 (Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan).
- PQRS #154 (Falls: Risk Assessment).
- PQRS #155 (Falls: Plan of Care).
- PQRS #182 (Functional Outcome Assessment).
- PQRS #240 (Childhood Immunization Status).
- PQRS #318 (Falls: Screening for Fall Risk).
- PQRS #400 (One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk).

While we are proposing to remove the above listed measures from the cross-cutting measure set, these measures are being proposed to be available as individual quality measures available for MIPS reporting, some of which have proposed substantive changes. The proposed MIPS cross-cutting measure set can be found in Table C of the appendix of this proposed rule and will be available on the CMS Web site.

e. Resource Use Performance Category

(1) Background

(a) General Overview and Strategy

Measuring resource use is an integral part of measuring value. We envision the measures in the MIPS resource use performance category would provide MIPS eligible clinicians with the information they need to provide appropriate care to their patients and enhance health outcomes. In implementing the resource use performance category, we propose to start with existing condition and episode-based measures, and the total per capita costs for all attributed beneficiaries measure (total per capita cost measure). All resource use measures would be adjusted for geographic payment rate adjustments and beneficiary risk factors. In addition, a specialty adjustment would be applied to the total per capita cost measure. As detailed in section II.E.6.a.3 of this proposed rule, all of the measures attributed to a MIPS eligible clinician or group would be weighted equally within the resource use performance category, and there would be no minimum number of measures required to receive a score under the resource use performance category. We plan to draw on standards for measure reliability, patient attribution, risk adjustment, and payment standardization from the Physician Value-based Payment Modifier (Value Modifier or VM) as well as the Physician Feedback Program, as we believe many of the same measurement principles for cost measurement in the VM are applicable for measurement in the resource use performance category in MIPS.

All measures used under the resource use performance category would be derived from Medicare administrative claims data and as a result, participation would not require use of a data submission mechanism.

We plan to continue developing care episode groups, patient condition groups, and patient relationship categories (and codes for such groups and categories). We plan to incorporate new measures as they become available and will give the public the opportunity to comment on these provisions through future notice and comment rulemaking. We also will closely examine the recommendations from the HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) study, when they are available, on the issue of risk adjustment for socioeconomic status on quality measures and resource use as required by section 2(d) of the IMPACT Act and incorporate them as feasible and appropriate through future rulemaking, under section 1848(q)(1)(G) of the Act.

(b) MACRA Requirements

Section 1848(q)(2)(A)(ii) of the Act establishes "resource use" as a performance category under the MIPS. Section 1848(q)(2)(B)(ii) of the Act describes the measures of the resource use performance category as the measurement of resource use for a MIPS performance period under section1848(p)(3) of the Act, using the methodology under section 1848(r) of the Act as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Part D.

As discussed in section II.E.5.e.(1)(c) of this proposed rule, we previously established in rulemaking a value-based payment modifier, as required by section 1848(p) of the Act, that provides for differential payment to a physician or a group of physicians under the Physician Fee Schedule based on the quality of care furnished compared to cost. For the evaluation of costs of care, section 1848(p)(3) refers to appropriate measures of costs established by the Secretary that eliminate the effect of geographic adjustments in payment rates and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals, such as to recognize that less healthy individuals may require more intensive interventions) and other factors determined appropriate by the Secretary.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for resource use measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups. That section provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). We are required to take into account several factors when establishing these groups. For care episode groups, we must consider the patient's clinical problems at the time items and services are furnished during an episode of care, such as clinical conditions or diagnoses, whether or not inpatient hospitalization occurs, the principal procedures or services furnished, and other factors determined appropriate by the Secretary. For patient condition groups, we must consider the patient's clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period), and other factors determined appropriate. We are required to post on the CMS Web site a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently post on the Web site an operational list of such groups and codes. As required by section 1848(r)(2)(H) of the Act, not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate.

To facilitate the attribution of patients and episodes to one or more clinicians, section 1848(r)(3) of the Act requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. These categories shall include different relationships of the clinician to the patient and reflect various types of responsibility for and frequency of furnishing care. We are required to post on the CMS Web site a draft list of patient relationship categories and codes for solicitation of input from stakeholders, and subsequently post on the Web site an operational list of such categories and codes. As required by section 1848(r)(3)(F) of the Act, not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate.

Section 1848(r)(4) of the Act requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall, as determined appropriate by the Secretary, include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories under sections 1848(r)(2) and (3) of the Act, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner).

Under section 1848(r)(5) of the Act, to evaluate the resources used to treat patients, the Secretary shall, as determined appropriate, use the codes reported on claims under section 1848(r)(4) of the Act to attribute patients to one or more physicians and applicable practitioners and as a basis to compare similar patients, and conduct an analysis of resource use. In measuring such resource use, the Secretary shall use per patient total allowed charges for all services under Parts A and B (and, if the Secretary determines appropriate, Part D) and may use other measures of allowed charges and measures of utilization of items and services. The Secretary shall seek comments through one or more mechanisms (other than notice and comment rulemaking) from stakeholders regarding the resource use methodology established under section 1848(r)(5) of the Act.

On October 15, 2015, as required by section 1848(r)(2)(B) of the Act, we posted on the CMS Web site for public comment a list of the episode groups developed under section 1848(n)(9)(A) of the Act with a summary of the background and context to solicit stakeholder input as required by section 1848(r)(2)(C) of the Act. That posting is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html*. The public comment period closed on February 15, 2016.

(c) Relationship to the Value Modifier

Currently, the physician value-based payment modifier established under section 1848(p) of the Act utilizes six cost measures (see 42 CFR 414.1235): (1) A total per capita costs for all-attributed beneficiaries measure (which we will refer to as the total per capita cost measure); (2) a total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease (COPD) measure; (3) a total per capita costs for all attributed beneficiaries with congestive heart failure (CHF) measure; (4) a total per capita costs for all attributed beneficiaries with coronary artery disease (CAD) measure; (5) a total per capita costs for all attributed beneficiaries with diabetes mellitus (DM) measure; and (6) a Medicare Spending Per Beneficiary (MSPB) measure.

Total per capita costs include payments under both Part A and Part B, but do not include Medicare payments under Part D for drug expenses. All cost measures for the VM are attributed at the physician group and solo practice level using the Medicare-enrolled billing TIN under a two-step attribution methodology. They are risk-adjusted and payment-standardized, and the expected cost is adjusted for the TIN's specialty composition. We refer readers to our discussions of these total per capita cost measures (76 FR 73433 through 73434, 77 FR 69315 through 69316), MSPB measure (78 FR 74774 through 74780, 80 FR 71295 through 71296), payment standardization methodology (77 FR 69316 through 69317), risk adjustment methodology (77 FR 69317 through 69318), and specialty adjustment methodology (78 FR 74781 through 74784) in earlier rulemaking for the VM. More information about these total per capita cost measures may be found in documents under the links titled "Measure Information Form: Overall Total Per Capita Cost Measure," "Measure Information Form: Condition-Specific Total Per Capita Cost Measures," and "Measure Information Form: Medicare Spending Per

Beneficiary Measure" available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeedbackprogram/valuebasedpaymentmodifier.html.*

The total per capita cost measures use a two-step attribution methodology that is similar, but not exactly the same, as the assignment methodology used for the Shared Savings Program. The attribution focuses on the delivery of primary care services (77 FR 69320) by both primary care clinicians and specialists. The MSPB measure has a different attribution methodology. It is attributed to the TIN that provides the plurality of Medicare Part B claims (as measured by allowable charges) during the index inpatient hospitalization. We refer readers to the discussion of our attribution methodologies (77 FR 69318 through 69320, 79 FR 67960 through 67964) in prior rulemaking for the VM.

These total per capita cost measures include payments for a calendar year and have been reported to TINs for several years through the Quality and Resource Use Reports (QRURs), which are issued as part of the Physician Feedback Program under section 1848(n) of the Act. The total per capita cost measures have been used in the calculation of the VM payment adjustments beginning with the 2015 payment adjustment period and the MSPB measure has been used in the calculation of the VM payment adjustments beginning with the 2016 payment adjustment period. More information about the current attribution methodology for these measures is available in the "Fact Sheet for Attribution in the Value-Based Payment Modifier Program" document available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeedbackprogram/valuebasedpaymentmodifier.html.*

In the MIPS and APMs RFI (80 FR 59102 through 59113), we solicited feedback on the resource use performance category. Commenters directed our attention towards the "2015 Value-Based Payment Modifier Program Experience Report" (document available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2015-VM-Program-Experience-Rpt.pdf*) for data demonstrating that physicians treating the largest shares of the Medicare's sickest patients are most likely to incur downward adjustments under the current program. Commenters suggested that CMS could risk adjust cost measures for differences in beneficiary characteristics impacting health and cost outcomes, and suggested that cost measure benchmarks could be stratified so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles. Commenters also expressed concern that current attribution methods are holding many clinicians accountable for costs they have no control over, while other clinicians have no patients attributed and no way of calculating accurate scores. Commenters generally believe episode-based costs could provide a more accurate measure in calculating resource use and comparing clinicians based on the cost of patient treatment episodes. Many commenters agreed that if properly selected and designed, measures tied to episodes of care could increase the relevance, reliability, and applicability of resource use measures and make feedback reports more actionable. However, in order for clinicians to be responsible for resource use, including episode-based costs, commenters strongly emphasized the need for access to timely and actionable information regarding these costs. Commenters have expressed concern that because certain VM measures were developed for hospitals they are not properly applied to clinician practices, which do not have Medicare patient populations large enough or heterogeneous enough to produce an accurate picture for resource use. Commenters requested that CMS make an effort to use resource measures which have been tested for use in clinician practices. Commenters supported development of new measures based on clinical guidelines and/or appropriate use criteria (AUC), and support the related "Choosing Wisely" campaign. In future years, individual specialties might decide to use AUC or "Choosing Wisely" guidelines in the creation of resource use measures applicable to their members. In these cases, CMS could consider adoption of evidence-based measures developed through a multi-specialty, clinician-led process.

(2) Weighting in the Composite Performance Score

As required by section 1848(q)(5)(E)(i)(II)(bb) of the Act, the resource use performance category shall make up no more than 10 percent of the CPS for the first MIPS payment year (CY 2019) and not more than 15 percent of the CPS the second MIPS payment year (CY 2020). Therefore, we propose at § 414.1350 that the resource use performance category would make up 10 percent of the CPS for the first MIPS payment year (CY 2019) and 15 percent of the CPS for the second MIPS payment year (CY 2020). As required by section 1848(q)(5)(E)(i)(II)(aa) of the Act and proposed at § 414.1350, starting with the third MIPS payment year and for each MIPS payment year thereafter, the resource use performance category would make up 30 percent of the CPS.

(3) Resource Use Criteria

As discussed above in section II.E.5.a. of this proposed rule, performance in the resource use performance category would be assessed using measures based on administrative Medicare claims data. At this time, we are not proposing any additional data submissions for the resource use performance category. As such, MIPS eligible clinicians and groups would be assessed based on resource use for Medicare patients only and only for patients that are attributed to them. MIPS eligible clinicians or groups that do not have enough attributed cases to meet or exceed the case minimums proposed in sections II.E.5.e.(3)(a)(ii) and II.E.5.e.(3)(b)(ii) would not be measured on resource use. For more discussion of MIPS eligible clinicians and groups without a resource use performance category score, please refer to II.E.6.a.(3)(d) and II.E.6.b.

(a) Value Modifier Cost Measures Proposed for the MIPS Resource Use Performance Category

For purposes of assessing performance of MIPS eligible clinicians on the resource use performance category, we propose at § 414.1350 to specify resource use measures for a performance period. For the CY 2017 MIPS performance period, we propose to utilize the total per capita cost measure, the MSPB measure, and several episode-based measures discussed in section II.E.5.e.3.b. of this proposed rule for the resource use performance category. The total per capita costs measure and the MSPB measure are described above in section II.E.5.e.(1)(c) of this proposed rule.

We propose including the total per capita cost measure as it is a global measure of all Part A and Part B resource use during the performance period and inclusive of the four condition specific measures under the VM (chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and diabetes mellitus) for which performance tends to be correlated and its inclusion was supported by commenters on the MIPS and APMs RFI (80 FR 59102 through 59113). We also anticipate that MIPS eligible clinicians are familiar with the total per capita cost measure as the measure has been in the VM since 2015 and feedback has been reported through the annual QRUR to all groups starting in 2014.

We propose to adopt the MSPB measure because by the beginning of the initial MIPS performance period in 2017, we believe most MIPS eligible clinicians will be familiar with the measure in the VM or its variant under the Hospital Value Based Purchasing program. However, we propose two technical changes to the MSPB measure calculations for purposes of its adoption in MIPS which are discussed in the reliability section II.E.5.e.3.a.ii. of this proposed rule.

We propose to use the same methodologies for payment standardization, and risk adjustment for these measures for the resource use performance category as are defined for the VM. For more details on the previously adopted payment standardization methodology see 77 FR 69316 through 69317. For more details on the previously adopted risk adjustment methodology see 77 FR 69317 through 69318.

We are not proposing to include the VM total per capita cost measures for the four condition-specific groups (chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and diabetes mellitus). Instead, we are generally proposing to assess performance as part of the episode-based measures proposed under section II.E.5.e.3.b. of this proposed rule. This shift is in response to feedback received as part of the MIPS and APMs RFI (80 FR 59102 through 59113). In the MIPS and APMs RFI, commenters stated that they do not believe the existing condition-based measures under the VM are relevant to their practice and expressed support for episode-based measures under MIPS.

(i) Attribution

In the VM, all cost measures are attributed to a TIN. In MIPS, however, we are proposing to evaluate performance at the individual and group levels. Please refer to section II.E.5.e.(3)(c) of this proposed rule, for our proposals to address attribution differences for individuals and groups. For purposes of this section, we will use the general term MIPS eligible clinicians to indicate attribution for individuals or groups.

For the MSPB measure, we propose to use attribution logic that is similar to what is used in the VM. MIPS eligible clinicians with the plurality of claims (as measured by allowable charges) for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period would be assigned the episode. The only difference from the VM attribution methodology would be that the MSPB measure would be assigned differently for individuals than for groups. For the total per capita cost measure, we propose to use a two-step attribution methodology that is similar to the methodology used in the 2017 and 2018 VM. We also propose to have the same two-step attribution process for the claims-based population measures in the quality performance category (section II.E.5.b.6.), CMS Web Interface measures, and CAHPS for MIPS. However, we also propose to make some modifications to the primary care services definition that is used in the attribution methodology to align with policies adopted under the Shared Savings Program.

The VM currently defines primary care services as the set of services identified by the following HCPCS/CPT codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). We propose to update this set to include new care coordination codes that have been implemented in the Medicare Physician Fee Schedule: Transitional care management (TCM) codes (CPT codes 99495 and 99496) and the chronic care management (CCM) code (CPT code 99490). These services were added to the primary care service definition used by the Shared Saving Program in June 2015 (80 FR 32746 through 32748). We believe that these care coordination codes would also be appropriate for assigning services in the MIPS.

In the CY 2016 PFS final rule, the Shared Saving Program also finalized another modification to the primary care service definition: To exclude nursing visits that occur in a skilled nursing facility (SNF) (80 FR 71271 through 71272). Patients in SNFs (POS 31) are generally shorter stay patients who are receiving continued acute medical care and rehabilitative services. While their care may be coordinated during their time in the SNF, they are then transitioned back to the community. Patients in a SNF (POS 31) require more frequent practitioner visits—often from 1 to 3 times a week. In contrast, patients in nursing facilities (NFs) (POS 32) are almost always permanent residents and generally receive their primary care services in the facility for the duration of their life. Patients in the NF (POS 32) are usually seen every 30 to 60 days unless medical necessity dictates otherwise. We believe that it would be appropriate to follow a similar policy in MIPS; therefore, we propose to exclude services billed under CPT codes 99304 through 99318 when the claim includes the POS 31 modifier from the definition of primary care services.

We believe that making these two modifications would help align the primary care service definition between MIPS and Shared Savings Program and would improve the results from the 2-step attribution process.

We note, however, that while we are aligning the definition for primary care services, the 2-step attribution for MIPS would be different than the one used for the Shared Saving Program. We believe there are valid reasons to have differences between MIPS and the Shared Savings Program attribution. For example, as discussed in CY 2015 PFS final rule (79 FR 67960 through 67962), we eliminated the primary care service pre-step that is statutorily required for the Shared Savings Program from the VM. We noted that without the pre-step, the beneficiary attribution method would more appropriately reflect the multiple ways in which primary care services are provided, which are not limited to physician groups. As MIPS eligible clinicians include more than physicians, we continue to believe it is appropriate to exclude the pre-step.

In addition, in the 2015 Shared Saving Program final rule, we finalized a policy for the Shared Savings Program that we did not extend to the VM 2-step attribution: to exclude select specialties (such as several surgical specialties) from the second attribution step (80 FR 32749 through 32754). We do not believe it is appropriate to restrict specialties from the second attribution step for MIPS. If such a policy were adopted under MIPS, then all specialists on the exclusion list, unless they were part of a multispecialty group, would automatically be excluded from measurement on the total per capita cost measure, as well as on the claims-based population measures which rely on the same 2-step attribution. While we do not believe that many MIPS eligible clinicians or clinician groups with these specialties would be attributed enough cases to meet or exceed the case minimum, we believe that an automatic exclusion could remove some MIPS eligible clinicians and groups that should be measured for resource use.

We request comments on these proposed changes.

(ii) Reliability

Additionally, we seek to ensure that MIPS eligible clinicians and groups are measured reliably; therefore, we intend to use the 0.4 reliability threshold currently applied to measures under the

VM to evaluate their reliability. A 0.4 reliability threshold standard means that the majority of MIPS eligible clinicians and groups who meet the case minimum required for scoring under a measure have measure reliability scores that exceed 0.4. We generally consider reliability levels between 0.4 and 0.7 to indicate "moderate" reliability and levels above 0.7 to indicate "high" reliability. In cases where we have considered high participation in the applicable program to be an important programmatic objective, such as the Hospital VBP Program, we have selected this 0.4 moderate reliability standard. We believe this standard ensures moderate reliability but does not substantially limit participation.

To ensure sufficient measure reliability for the resource use performance category in MIPS, we also propose at § 414.1380(b)(2)(ii) to use the minimum of 20 cases for the total per capita cost measure, the same case minimum that is being used for the VM. An analysis in the CY 2016 PFS final rule (80 FR 71282) confirms that this measure has high average reliability for solo practitioners (0.74) as well as for groups with more than 10 professionals (0.80).

In the CY 2016 PFS final rule, we finalized a policy that increases the minimum cases for the MSPB measure from 20 to 125 cases (80 FR 71295 through 71296) due to reliability concerns with the measure including the specialty adjustment. That said, we recognize that a case size increase of this nature also may limit the ability of MIPS eligible clinicians to be scored on MSPB, and have been evaluating alternative measure calculation strategies for potential inclusion under MIPS that better balance participation, accuracy, and reliability. As a result of this, we are proposing two modifications to the MSPB measure.

The first technical change we are proposing is to remove the specialty-adjustment from the MSPB measure's calculation. As currently reported on the QRURs, the MSPB measure is risk adjusted to ensure that these comparisons account for case-mix differences between practitioners' patient populations and the national average. It is unclear that the current additional adjustment for physician specialty improves the accounting for case-mix differences for acute care patients, and thus, may not be needed.

The second technical change we propose is to modify the cost ratio used within the MSPB equation to evaluate the difference between observed and expected episode cost at the episode level before comparing the two at the individual or group level. In other words, rather than summing all of the observed costs and dividing by the sum of all the expected costs, we would take the observed to expected cost ratio for each MSPB episode assigned to the MIPS eligible clinician or group and take the average of the assigned ratios. As we did previously, we would take the average for the MIPS eligible clinician or group and multiply it by the average of observed costs across all episodes nationally.

Our analysis, which is based on all Medicare Part A and B claims data for beneficiaries discharged from an acute inpatient hospital between January 1, 2013 and December 1, 2013, indicates that these two changes would improve the MSPB measure's ability to calculate costs and the accuracy with which it can be used to make clinician-level performance comparisons. We also believe that these changes would help ensure the MSPB measure can be applied to a greater number of MIPS eligible clinicians while still maintaining its status as a reliable measure. More specifically, our analysis indicates that after making these changes to the MSPB measure's calculations, the MSPB measure meets the desired 0.4 reliability threshold used in the VM for over 88 percent of all TINs with a 20 case minimum, including solo practitioners. While this percentage is lower than our current policy for the VM (where virtually all TINs with 125 or more episodes have moderate reliability), setting the case minimum at 20 allows for an increase in participation in the MSPB measure. Therefore, we propose at § 414.1380(b)(2)(ii) to use a minimum of 20 cases for the MSPB measure. As noted previously, we consider expanded participation of MIPS eligible clinicians, particularly individual reporters, to be of great import for the purposes of transitioning to MIPS and believe that this justifies a slight decrease of the percentage of TINs meeting the reliability threshold.

We welcome public comment on these proposals.

(b) Episode-Based Measures Proposed for the MIPS Resource Use Performance Category

As noted in the previous section, we are proposing to calculate several episode-based measures for inclusion in the resource use performance category. Groups have received feedback on their performance on episode-based measures through the Supplemental Quality and Resource Use Report (sQRUR), which are issued as part of the Physician Feedback Program under section 1848(n) of the Act; however, these measures have not been used for payment adjustments through the VM. Several stakeholders expressed in the MIPS and APMs RFI the desire to transition to episode-based measures and away from the general total per capita measures used in the VM. Therefore, in lieu of using the total per capita cost measures for populations with specific conditions that are used for the VM, we are proposing episode-based measures for a variety of conditions and procedures that are high cost, have high variability in resource use, or are for high impact conditions. In addition, as these measures are payment standardized and risk adjusted, we believe they meet the statutory requirements for appropriate measures of cost as defined in section 1848(p)(3) of the Act because the methodology eliminates the effects of geographic adjustments in payment rates and takes into account risk factors.

We also reiterate that while we transition to using episode-based measures for payment adjustments, we will continue to engage stakeholders through the process specified in section 1848(r)(2) of the Act to refine and improve the episodes moving forward.

As noted earlier, we have provided performance information on episode-based measures to MIPS eligible clinicians through the Supplemental Quality and Resource Use Reports (sQRURs), which are released in the Fall. The sQRURs provide groups and solo practitioners with information to evaluate their resource utilization on conditions and procedures that are costly and prevalent in the Medicare FFS population. To accomplish this goal, various episodes are defined and attributed to one or more groups or solo practitioners most responsible for the patient's care. The episode-based measures include Medicare Part A and Part B payments for services determined to be related to the triggering condition or procedure. The payments included are standardized to remove the effect of differences in geographic adjustments in payment rates and incentive payment programs and they are risk adjusted for the clinical condition of beneficiaries. Although the sQRURs provide detailed information on these care episodes, the calculations are not used to determine a TIN's VM payment adjustment and are only used to provide feedback.

We propose to include in the resource use performance category several clinical condition and treatment episode-based measures that have been reported in the sQRUR or were included in the list of the episode groups developed under section 1848(n)(9)(A) of the Act published on the CMS Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html*. The identified episode-based measures have been tested and previously published. Tables 4 and 5 list the 41 clinical condition and treatment episode-based measures proposed for the CY 2017 MIPS performance period, as well as whether the episodes have previously been reported in a sQRUR.

The measures listed in Table 4 were developed under section 1848(n)(9)(A) of the Act, which required the Secretary to develop an episode grouper that combines separate but clinically related items and services into an episode of care for an individual, as appropriate, and provide reports on utilization to physicians (episode grouping Method A). The proposed measures accommodate both chronic and acute procedure episodes. The measures are also specifically designed to accommodate episodes that are initiated by physician claims, and section 1848(r)(4) of the Act requires claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, to include (as determined appropriate by the Secretary) the applicable codes established for care episode groups, patient condition groups, and patient relationship categories. The episodes and logic have undergone detailed and rigorous evaluation by an independent evaluation contractor and CMS also reviewed for clinical validity.

Attribution and reliability for the measures are discussed later in this section. Information about how the measures are constructed can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html* under the link for "Method A—Technical." Detailed episode logic can be found under the "Method A" link on the same page.

TABLE 4: Proposed Clinical Condition and Treatment Episode-based Measures Developed Under Section 1848(n)(9)(A) of the Act (Method A)

Clinical Topic, File Name	Episode Name, File Name, and Description	Included in 2014 sQRUR
Breast		
1	**Mastectomy for Breast Cancer** Px - breast - resect – mastectomy.xls Mastectomy for Breast Cancer episode is triggered by a patient's claim with any of the interventions assigned as Mastectomy trigger codes. Mastectomy can be triggered by either an ICD procedure code, or CPT codes in any setting (e.g., hospital, surgical center).	Yes
Cardiovascular		
2	**Acute Myocardial Infarction (AMI) without PCI/CABG** CV - IHD - Acute Myocardial Infarction (AMI).xls Acute Myocardial Infarction (AMI) episode is triggered by an inpatient hospital claim with a principal diagnosis of any AMI trigger code. AMI episodes would be stratified. The AMI condition episode without CABG or PCI is the stratification that will be measured.	Yes
3	**Abdominal Aortic Aneurysm** cvas - arterial - abdominal aortic aneurysm.xls Abdominal Aortic Aneurysm (AAA) episode is triggered by two (2) E&Ms with a principal or secondary diagnosis of any AAA trigger code occurring within 30 calendar days. This episode is intended to capture all services related to the medical management and treatment of a AAA.	No
4	**Thoracic Aortic Aneurysm** cvas - arterial - thoracic aortic aneurysm_Method A.xls Thoracic Aortic Aneurysm (TAA) episode is triggered by two (2) E&Ms with a principal or secondary diagnosis of any TAA trigger code occurring within 30 calendar days. This episode is intended to capture all services related to the medical management and treatment of a TAA.	No
5	**Aortic/Mitral Valve Surgery** Px - cardiac - valve surgery (aortic and mitral)_Method_A.xls Open heart valve surgery (Valve) episode is triggered by a patient claim with any of Valve trigger codes.	Yes
6	**Atrial Fibrillation (AFib)/Flutter, Acute Exacerbation** cvas - heart rhythm - atrial fibrillation-flutter(acute)_Method_A.xls Acute Atrial fibrillation/flutter (AfibAcute) episode is triggered by a diagnostic code on patient's inpatient claim on principal position as AfibAcute trigger code.	Yes
7	**Atrial Fibrillation (AFib)/Flutter, Chronic** cvas - heart rhythm - atrial fibrillation-flutter (chronic)_Method_A.xls Chronic Atrial fibrillation/flutter (AfibChronic) episode is triggered by a diagnostic code on patient's inpatient claim on principal position as AfibChronic trigger code or by E&M service in other setting. This identification rule distinguishes between an Acute and chronic episodes of atrial fibrillation/flutter, besides having different closing rules.	No

Clinical Topic, File Name	Episode Name, File Name, and Description	Included in 2014 sQRUR
8	**Coronary Artery Bypass Graft (CABG)** Px - cardiac - coronary art proc - cabg_Method_A.xls Coronary Artery Bypass Grafting (CABG) episode is triggered by an inpatient hospital claim with any of CABG trigger codes for coronary bypass. CABG generally is limited to facilities with a Cardiac Care Unit (CCU); hence there are no episodes or comparisons in other settings.	Yes
9	**Heart Failure, Acute Exacerbation** cvas - cardiac - heart failure (acute)_Method_A.xls Acute heart failure (HFAcute) episode is triggered by an inpatient hospital claim with a principal diagnosis of any HFAcute trigger codes.	Yes
10	**Heart Failure, Chronic** cvas - cardiac - heart failure (chronic)_Method_A.xls Chronic heart failure (HFChronic) episode is triggered by an inpatient hospital claim with a principal diagnosis of any HFChronic trigger codes.	No
11	**Ischemic Heart Disease (IHD), Chronic** CV - IHD (chronic)_Method_A.xls Chronic ischemic heart disease (IHDChronic) episode is triggered by an inpatient hospital claim with a principal diagnosis of any IHDChronic trigger codes. Moreover, IHDChronic is among those episodes that have a more complex triggering rule allowing for an E&M service with a related confirming intervention to open this episode in outpatient setting.	No
12	**Pacemaker** Px - cardiac - heart rhythm proc - pacemaker_Method_A.xls Cardiac pacemaker insertion (Pacemaker) episode is triggered by claim with any of the interventions assigned as Pacemaker trigger codes.	Yes
13	**Percutaneous Cardiovascular Intervention (PCI):** Px - cardiac - coronary art proc - pci_Method_A.xls Percutaneous Cardiovascular Intervention (PCI) episode is triggered by claim with any of the interventions assigned as PCI trigger codes. PCI is one of a few episodes that can be triggered by selected MS-DRG codes on a hospital claim, given that the episode can consist largely of a hospital service, and the MS-DRG can correspond closely to the procedure itself. PCI, formerly known as angioplasty with stent, is a non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis.	Yes
Cerebrovascular		
14	**Ischemic Stroke** neur - cerebrovasc - ischemic cva-stroke_Method_A.xls Ischemic stroke (StrokIsc) episode is triggered by an inpatient hospital claim with a principal diagnosis of any StrokIsc trigger codes.	Yes
15	**Carotid Endarterectomy** Px - neuro - vascular - carotid endarterectomy_Method_A.xls Carotid endarterectomy (Carotid) episode is triggered by an inpatient hospital claim with any of the interventions assigned as Carotid trigger codes. Carotid can be triggered by either an ICD procedure code or CPT codes in any setting.	Yes
Gastrointestinal		

Clinical Topic, File Name	Episode Name, File Name, and Description	Included in 2014 sQRUR
16	**Cholecystitis** gi - hepatobiliary - cholecystitis (chronic)_Method A.xls Cholecystitis (CholCyst) episode is triggered by two (2) E&Ms with a principal or secondary diagnosis of any CholCyst trigger code occurring within 30 calendar days. This episode is intended to capture all services related to the medical management and treatment of a CholCyst.	No
17	***Clostridium difficile* Colitis** gi - colorectal - c-difficile colitis_Method A.xls C-Difficile Colitis (Cdiff) episode is triggered by: 1. An inpatient facility claim with a principal diagnosis of any Cdiff trigger code OR 2. Two (2) E&Ms with a principal or secondary diagnosis of any Cdiff trigger code occurring within 30 calendar days.	No
18	**Diverticulitis of Colon** gi - colorectal - diverticulitis of colon_Method A.xls Diverticulitis of Colon (DivColon) episode is triggered by: 1. An inpatient facility claim with a principal diagnosis of any DivColon trigger code OR 2. Two (2) E&Ms with a principal or secondary diagnosis of any DivColon trigger code occurring within 30 calendar days.	No
Genitourinary		
19	**Prostatectomy for Prostate Cancer** Px - gu - prostate proc - prostatectomy_Method_A.xls Definitive Prostatectomy for prostate cancer (Prostect) episode is a distinguished procedure from transurethral resection (TURP) and other procedures for on neoplastic disease of the prostate. This episode is triggered by an inpatient hospital claim with any of the interventions assigned as Prostect trigger codes. Prostect can be triggered by either an ICD procedure code, or CPT codes in any setting.	Yes
Infectious Disease		
20	**Kidney and Urinary Tract Infection (UTI)** uro-gen - other-nos – uti.xls Acute heart failure (UTI_IP) episode is triggered by an inpatient hospital claim with a principal diagnosis of any UTI_IP trigger codes.	No
Metabolic		
21	**Osteoporosis** msk - other-nos - osteoporosis_Method A.xls Osteoporosis (Osteopor) episode is triggered by two (2) E&Ms with a principal or secondary diagnosis of any Osteoporosis trigger code occurring within 30 calendar days. This episode is intended to capture all services related to the medical management and treatment of Osteopor.	No
Neurology		
22	**Parkinson Disease** neur - brain - parkinsons ds_Method A.xls Parkinsons disease (Parkinsons) episode is triggered by two (2) E&Ms with a principal or secondary diagnosis of any Parkinsons trigger code occurring within 30 calendar days. This episode is intended to capture all services related to the medical management and treatment of Parkinsons.	No

Clinical Topic, File Name	Episode Name, File Name, and Description	Included in 2014 sQRUR
Musculoskeletal		
23	**Rheumatoid Arthritis** gen-unsp - other-nos - rheumatoid arthritis_Method A.xls Rheumatoid Arthritis (RA) episode is triggered by two (2) E&Ms with a principal or secondary diagnosis of any RA trigger code occurring within 30 calendar days. This episode is intended to capture all services related to the medical management and treatment of RA.	No
24	**Hip/Femur Fracture or Dislocation Treatment, Inpatient (IP)-Based** Px - ortho - treat fx-disloc - hip-femur - open_Method_A.xls Fracture/dislocation of hip/femur (HIPFxTx) episode is triggered by a patient claim with any of the interventions assigned as HIPFxTx trigger codes. HIPFxTx can be triggered by either an ICD procedure code or CPT codes in any setting.	Yes
25	**Hip Replacement or Repair** Px - ortho - hip proc - replacement_Method_A.xls Hip replacement procedure (HipRepRev) episode is triggered by a patient claim with any of the interventions assigned as HipRepRev trigger codes. HipRepRev can be triggered by either an ICD procedure code, CPT, or HCPC codes in any setting.	No
26	**Knee Arthroplasty (Replacement)** Px - ortho - knee proc - replacement_Method_A.xls Knee replacement procedure (KneeRepRev) episode is triggered by a patient claim with any of the interventions assigned as KneeRepRev trigger codes. KneeRepRev can be triggered by either ICD procedure codes or CPT codes in any setting.	No
27	**Spinal Fusion** Px - ortho - spine proc – lumbar.xls Spinal Fusion (SpineLumb) episode is triggered by a patient's claim with any of the interventions assigned as SpineLumb trigger codes. SpineLumb can be triggered by either an ICD procedure code, or CPT codes in any setting (e.g., hospital, surgical center).	No
Respiratory		
28	**Asthma/Chronic Obstructive Pulmonary Disease (COPD), Acute Exacerbation** chest - airway lungs - asthma-copd (acute)_Method_A.xls Acute [exacerbation of] asthma/COPD (COPDAcute) episode is triggered by an inpatient hospital claim with a principal diagnosis of any COPDAcute trigger codes.	Yes
29	**Asthma/Chronic Obstructive Pulmonary Disease (COPD), Chronic** chest - airway lungs - asthma-copd (chronic)_Method_A.xls Acute [exacerbation of] asthma/COPD (COPDChronic). This episode is triggered by an inpatient hospital claim with a principal diagnosis of any COPDChronic trigger codes. Moreover, COPDChronic is among those episodes that have a more complex triggering rule allowing for an E&M service with a related confirming intervention to open this episode in outpatient setting.	No

Clinical Topic, File Name	Episode Name, File Name, and Description	Included in 2014 sQRUR
30	**Pneumonia, Community Acquired, Inpatient (IP)-Based** chest - pneumonia - pneumonia acute, com acq (ip)_Method_A.xls Acute, community acquired pneumonia (inpatient) (PNE-IP) episode is triggered by claim with any of the interventions assigned as PNE-IP trigger codes. The grouper identification rule distinguishes between an inpatient and outpatient pneumonia episodes, besides different closing rules.	Yes
31	**Pneumonia, Community Acquired, Outpatient (OP)-Based** chest - pneumonia - pneumonia acute, com acq (op)_Method_A.xls Acute, community acquired pneumonia (inpatient) (PNE-IP) episode is triggered by claim with any of the interventions assigned as PNE-IP trigger codes. The grouper identification rule distinguishes between an inpatient and outpatient pneumonia episodes, besides different closing rules.	No
32	**Pulmonary Embolism, Acute** cvas - other-nos - acute pulmonary embolism_Method A.xls Acute Pulmonary Embolism (PE Acute) episode is triggered by: 1. An inpatient facility claim with a principal diagnosis of any PE Acute trigger code OR 2. Two (2) E&Ms with a principal or secondary diagnosis of any PE Acute trigger code occurring within 30 calendar days.	No
33	**Upper Respiratory Infection, Acute, Simple** chest - uri - acute uri simple_Method A.xls Acute URI Simplae (URIAcute) episode is triggered by: 1. An inpatient facility claim with a principal diagnosis of any URIAcute trigger code OR 2. Two (2) E&Ms with a principal or secondary diagnosis of any URIAcute trigger code occurring within 30 calendar days.	No
Vascular		
34	**Deep Venous Thrombosis of Extremity, NOS, Acute** cvas - venous - acute dvt extremity-nos_Method A.xls Acute DVT extremity/NOS (DVTAcute). This episode is triggered by: 1. An inpatient facility claim with a principal diagnosis of any DVTAcute trigger code OR 2. Two (2) E&Ms with a principal or secondary diagnosis of any DVTAcute trigger code occurring within 30 calendar days.	No

Table 5 shows a second set of proposed measures that were developed to complement previous CMS efforts and to provide additional episode types to report in the supplemental QRURs. These measures represent acute conditions and procedures that are costly and prevalent in the Medicare FFS population. These measures examine services independently, regardless of other episodes a patient may be experiencing, and episodes do not interact with each other (episode grouping Method B).

Some of the episode types listed in Table 5 have subtypes that provide additional clinical detail and improve the actionability of data reported on these episode types, as well as comparability to expected costs. All episode types were developed with clinical input and complement the existing MSPB measure currently used in the VM. In addition, all episode types were reported in 2014 sQRURs.

Information about how the measures are constructed can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html* under the link for "Method B—Technical." Detailed episode logic can be found under the "Method B" link on the same page.

TABLE 5: Additional Proposed Clinical Condition and Treatment Episode Measures (Method B)

Clinical Topic, File Name	Episode Name, File Name, and Description	Included in 2014 sQRUR
Gastrointestinal		
1	**Cholecystectomy and Common Duct Exploration** Cholecystectomy_Episode_Definitions_MethodB_2015Sept.xlsx Episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day. Medical condition episodes are triggered by IP stays with specified MS-DRGs.	Yes
2	**Colonoscopy and Biopsy** Colonoscopy_Episode_Definitions_MethodB_2015Sept.xlsx Episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day. Medical condition episodes are triggered by IP stays with specified MS-DRGs.	Yes
3	**Transurethral Resection of the Prostate (TURP) for Benign Prostatic Hyperplasia** TURP_Episode_Definitions_MethodB_2015Sept.xlsx For procedural episodes, treatment services are defined as the services attributable to the MIPS eligible clinician or group managing the patient's care for the episode's health condition.	Yes
Infectious Disease		
4	**Kidney and Urinary Tract Infection (UTI)** KidneyUTI_Episode_Definitions_MethodB_2015Sept.xlsx Procedural episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day. Medical condition episodes are triggered by IP stays with specified MS-DRGs.	Yes
Ophthalmology		
5	**Lens and Cataract Procedures** Cataract_Episode_Definitions_MethodB_2015Sept.xlsx Procedural episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day.	Yes
Musculoskeletal		
6	**Hip Replacement or Repair** Hip_Rep_or_Repair_Episode_Definitions_MethodB_2015Sept.xlsx Procedural episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day.	Yes
7	**Knee Arthroplasty (Replacement)** Knee_Arthroplasty_Episode_Definitions_MethodB_2015Sept.xlsx Procedural episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day.	Yes

While we are proposing the measures listed in Tables 4 and 5 for the resource use performance category, we are uncertain as to how many of these measures we will ultimately include in the final rule. As these measures have never been used for payment purposes, we may choose to specify a subset of these measures in the final rule. We request public comment on which of the measures listed in Tables 4 and 5 to include in the final rule. In addition to considering public comments, we intend to consider the number of MIPS eligible clinicians able to be measured, the episode's impact on Medicare Part A and Part B spending, and whether the measure has been reported through sQRUR. In addition, while we do not believe specialty adjustment is necessary for the episode-based measures, we will continue to explore this further given the diversity of episodes. We seek comment on whether we should specialty adjust the episode-based measures.

(i) Attribution

For the episode-based measures listed in Tables 4 and 5, we propose to use the attribution logic used in the 2014 sQRUR (full description available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Detailed-Methods-2014SupplementalQRURs.pdf*), with modifications to adjust for whether performance is being assessed at an individual level or group level. Please refer to section

II.E.5.e.(3)(c) of this proposed rule for our proposals to address attribution differences for individuals and groups. For purposes of this section, we will use the general term MIPS eligible clinicians to indicate attribution for individuals or groups.

Acute condition episodes would be attributed to all MIPS eligible clinicians that bill at least 30 percent of inpatient evaluation and management (IP E&M) visits during the initial treatment, or "trigger event," that opened the episode. E&M visits during the episode's trigger event represent services directly related to the management of the beneficiary's acute condition episode. MIPS eligible clinicians that bill at least 30 percent of IP E&M visits are therefore likely to have been responsible for the oversight of care for the beneficiary during the episode. It is possible for more than one MIPS eligible clinician to be attributed a single episode using this rule. If an acute condition episode has no IP E&M claims during the episode, then that episode is not attributed to any MIPS eligible clinician.

Procedural episodes would be attributed to all MIPS eligible clinicians that bill a Medicare Part B claim with a trigger code during the trigger event of the episode. For inpatient procedural episodes, the trigger event is defined as the IP stay that triggered the episode plus the day before the admission to the IP hospital. For outpatient procedural episodes constructed using Method A, the trigger event is defined as the day of the triggering claim plus the day before and two days after the trigger date. For outpatient procedural episodes constructed using Method B, the trigger event is defined as only the day of the triggering claim. Any Medicare Part B claim or line during the trigger event with the episode's triggering procedure code is used for attribution. If more than one MIPS eligible clinician bills a triggering claim during the trigger event, the episode is attributed to each of the MIPS eligible clinicians. If co-surgeons bill the triggering claim, the episode is attributed to each MIPS eligible clinician. If only an assistant surgeon bills the triggering claim, the episode is attributed to the assistant surgeon or group. If an episode does not have a concurrent Part B claim with a trigger code for the episode, then that episode is not attributed to any MIPS eligible clinician.

(ii) Reliability

To ensure moderate reliability, we propose at § 414.1380(b)(2)(ii) to use the minimum of 20 cases for all episode-based measures listed in Tables 4 and 5. We propose to not include any measures that do not have average moderate reliability (at least 0.4) at 20 episodes.

(c) Attribution for Individual and Groups

In the VM and sQRUR, all resource use measurement was attributed at the solo practitioner and group level, as identified by TIN. In MIPS, however, we are proposing to evaluate performance at the individual and group levels. For MIPS eligible clinicians whose performance is being assessed individually across the other MIPS performance categories, we propose to attribute resource use measures using TIN/NPI rather than TIN. Attribution at the TIN/NPI level allows individual MIPS eligible clinicians, as identified by their TIN/NPI, to be measured based on cases that are specific to their practice, rather than being measured on all the cases attributed to the group TIN. For MIPS eligible clinicians that choose to have their performance assessed as a group across the other MIPS performance categories, we propose to attribute resource use measures at the TIN level (the group TIN under which they report). The logic for attribution would be similar whether attributing to the TIN/NPI level or the TIN level. As an alternative proposal, we seek comment on whether MIPS eligible clinicians that choose to have their performance assessed as a group should first be attributed at the individual TIN/NPI level and then have all cases assigned to the individual TIN/NPIs attributed to the group under which they bill. This alternative would apply one consistent methodology to both groups and individuals, compared to having a methodology that assigns cases using TIN/NPI for assessment at the individual level and another that assigns cases using only TIN for assessment at the group level. For example, the general attribution logic for MSPB is to assign the MSPB measure based on the plurality of claims (as measured by allowable charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure. Our proposed approach would determine "plurality of claims" separately for individuals and groups. For individuals, we would assign the MSPB measure using the "plurality of claims" by TIN/NPI, but for groups we would determine the "plurality of claims" by TIN. The alternative proposal, in contrast, would determine the "plurality of claims" by TIN/NPI for both groups and individuals. However, for individuals, only the MSPB measure attributed to the TIN/NPI would be evaluated, while for groups the MSPB measure attributed to any TIN/NPI billing under the TIN would be evaluated.

We request comment on this proposal and alternative considered.

(d) Application of Measures to Non-Patient Facing MIPS Eligible Clinicians

Section 101(c) of the MACRA added section 1848(q)(2)(C)(iv) to the Act, which requires the Secretary to give consideration to the circumstances of professional types who typically furnish services without patient facing interaction (non-patient-facing) when determining the application of measures and activities. In addition, this section allows the Secretary to apply alternative measures or activities to non-patient facing MIPS eligible clinicians that fulfill the goals of a performance category. Section 101(c) of the MACRA also added section 1848(q)(5)(F) to the Act, which allows the Secretary to re-weight MIPS performance categories if there are not sufficient measures and activities applicable and available to each type of eligible clinician involved.

For the 2017 MIPS performance period, we are not proposing any alternative measures for non-patient facing MIPS eligible clinicians or groups. This means that non-patient facing MIPS eligible clinicians or groups may not be attributed any resource use measures that are generally attributed to clinicians who have patient facing encounters with patients. We therefore anticipate that, similar to MIPS eligible clinicians or groups that do not meet the required case minimum for any resource use measures, many non-patient facing MIPS eligible clinicians may not have sufficient measures and activities available to report and would not be scored on the resource use performance category under MIPS. We refer readers to section II.E.6.b.2. of this proposed rule where we discuss how we would address performance category weighting for MIPS eligible clinicians or groups who do not receive a performance category score for a given performance category. We also intend to work with non-patient facing MIPS eligible clinicians and specialty societies to propose alternative resource use measures for non-patient facing MIPS eligible clinicians and groups under MIPS in future years. Lastly, we seek comment on how best to incorporate appropriate alternative resource use measures for all MIPS eligible clinician types, including non-patient facing MIPS eligible clinicians.

(e) Additional System Measures

Section 1848(q)(2)(C)(ii) of the Act, as added by section 101(c) of MACRA provides that the Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and resource use performance categories of MIPS. The Secretary, however, may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

We intend to align any facility-based MIPS measure decision across the quality and resource use performance categories to ensure consistent policies for MIPS in future years. We refer readers back to section II.E.5.b.5. of this proposed rule, which discusses our strategy and solicits comments related to this provision.

(4) Future Modifications to Resource Use Performance Category

In the future, we intend to consider how best to incorporate Part D costs into the resource use performance category, as described in section 1848(q)(2)(B)(ii) of the Act. We seek public comments on how we should incorporate those costs under MIPS for future years. We also intend to continue developing and refining episode groups for purposes of resource use performance category measure calculations.

f. Clinical Practice Improvement Activity (CPIA) Category

(1) Background

(a) General Overview and Strategy

The CPIA performance category focuses on one of our MIPS strategic goals, to use a patient-centered approach to program development that leads to better, smarter, and healthier care. We believe improving the health of all Americans can be accomplished by developing incentives and policies that drive improved patient health outcomes. CPIAs emphasize activities that have a proven association with improved health outcomes. The CPIA performance category also focuses on another MIPS strategic goal which is to use design incentives that drive movement toward delivery system reform principles and APMs. Another MIPS strategic goal we are striving to achieve is to establish policies that can be scaled in future years as the bar for improvement rises. Under the CPIA performance category we are proposing baseline requirements that will continue to have more stringent requirements in future years, and lay the groundwork for expansion towards continuous improvement over time.

(b) The MACRA Requirements

Section 1848(q)(2)(C)(v)(III) of the Act defines a CPIA as an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery, and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act requires the Secretary to specify CPIAs under subcategories for the performance period, which must include at least the subcategories specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act, and in doing so to give consideration to the circumstances of small practices (consisting of 15 or fewer clinicians), and practices located in rural areas and geographic health professional shortage areas (HPSAs).

Section 1848(q)(2)(C)(iv) of the Act generally requires the Secretary to give consideration to the circumstances of non-patient-facing MIPS eligible clinicians or groups and allows the Secretary, to the extent feasible and appropriate, to apply alternative measures and activities to such MIPS eligible clinicians and groups.

Section 1848(q)(2)(C)(v) of the Act required the Secretary to use a request for information (RFI) to solicit recommendations from stakeholders to identify CPIAs and specify criteria for such CPIAs, and provides that the Secretary may contract with entities to assist in identifying activities, specifying criteria for the activities, and determining whether MIPS eligible clinicians or groups meet the criteria set. In the MIPS and APMs RFI, we requested recommendations to identify activities and specify criteria for activities. In addition, we requested details on how data should be submitted, the number of activities, how performance should be measured, and what considerations should be made for small and/or rural practices. There were two overarching themes from the comments that we received. First, the majority of the comments indicated that all subcategories should be weighted equally and that MIPS eligible clinicians or groups should be allowed to select from whichever subcategories are most applicable to them during the performance period. Second, commenters supported inclusion of a diverse set of activities that are meaningful for individual MIPS eligible clinicians or groups. We have reviewed all of the comments that we received and have taken these recommendations into consideration while developing the proposed CPIA policies.

(2) Contribution to Composite Performance Score (CPS)

Section 1848(q)(5)(E)(i)(III) of the Act specifies that the CPIA performance category will account for 15 percent of the CPS, subject to the Secretary's authority to assign different scoring weights under section 1848(q)(5)(F) of the Act. Therefore, we propose at § 414.1355, that the CPIA performance category will account for 15 percent of the CPS.

Section 1848(q)(5)(C)(i) of the Act specifies that a MIPS eligible clinician or group that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, with respect to a performance period must be given the highest potential score for the CPIA performance category for the performance period. For a further description of APMs that have a certified patient centered-medical home designation, we refer readers to section II.E.5.h.

A patient-centered medical home will be recognized if it is a nationally recognized accredited patient-centered medical home, a Medicaid Medical Home Model, or a Medical Home Model. The NCQA Patient-Centered Specialty Recognition will also be recognized, which qualifies as a comparable specialty practice. Nationally recognized accredited patient-centered medical homes are recognized if they are accredited by: (1) The Accreditation Association for Ambulatory Health Care; (2) the National Committee for Quality Assurance (NCQA) PCMH recognition; (3) The Joint Commission Designation; or (4) the Utilization Review Accreditation Commission (URAC).[8] We refer readers to section II.F. of this proposed rule for further description of the Medicaid Medical Home Model or Medical Home Model.[9] The criteria for being a nationally recognized accredited patient-centered medical home is that it must be national in scope and must have evidence of being used by a large number of medical organizations as the model for their patient-centered medical home. We seek comment on our proposal for determining which practices would qualify as patient-centered medical homes. We also note that practices may receive a patient-centered medical home designation at a practice level, and that individual TINs may be composed of both undesignated practices and practices that have received a designation as a patient-centered medical home (for example, only one practice site has received patient-centered medical home designation in a TIN that includes five practice sites). For MIPS eligible clinicians who choose to report at the group level, reporting is required at the TIN level. We solicit comment on how to provide credit for patient-centered medical home designations in the calculation of the CPIA performance category score for groups when the designation only applies to a portion of the TIN (for example, to only one practice site in a TIN that is comprised of five practice sites).

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[8] Gans, D. (2014). *A Comparison of the National Patient-Centered Medical Home Accreditation and Recognition Programs.* Medical Group Management Association, *www.mgma.com.*

Section 1848(q)(5)(C)(ii) of the Act provides that MIPS eligible clinicians or groups who are participating in an APM (as defined in section 1833(z)(3)(C) of the Act) for a performance period must earn at least one half of the highest potential score for the CPIA performance category for the performance period. For further description of CPIA and the APM scoring standard for MIPS, we refer readers to section II.E.5.h. For all other MIPS eligible clinicians or groups, this section applies and we also refer readers to the scoring requirements for MIPS eligible clinicians and groups in section II.E.6. of this proposed rule.

Section 1848(q)(5)(C)(iii) of the Act provides that a MIPS eligible clinician or group must not be a MIPS eligible clinician or group required to perform activities in each CPIA subcategory or participate in an APM to achieve the highest potential score for the CPIA performance category.

Section 1848(q)(5)(B)(i) of the Act requires the Secretary to treat a MIPS eligible clinician or group that fails to report on an applicable measure or activity that is required to be reported, they will receive the lowest potential score applicable to the measure or activity.

(3) CPIA Data Submission Criteria

(a) Submission Mechanisms

For the purpose of submitting under the CPIA performance category, we proposed in section II.E.5.a. of this proposed rule to allow for submission of data for the CPIA performance category using the qualified registry, EHR, QCDR, CMS Web Interface and attestation data submission mechanisms. If technically feasible, we will use administrative claims data to supplement the CPIA submission. Regardless of the data submission method, all MIPS eligible clinicians or groups must select activities from the CPIA Inventory provided in Table H of the Appendices. We believe the proposed data submission methods will allow for greater access and ease in submitting data, as well as consistency throughout the MIPS program.

In addition, we propose at § 414.1360, that for the first year only, all MIPS eligible clinicians or groups, or third party entities such as health IT vendors, QCDRs and qualified registries that submit on behalf of a MIPS eligible clinician or group, must designate a yes/no response for activities on the CPIA Inventory. In the case where a MIPS eligible clinician or group is using a health IT vendor, QCDR, or qualified registry for their data submission, the MIPS eligible clinician or group will certify all CPIAs have been performed and the health IT vendor, QCDR, or qualified registry will submit on their behalf. An agreement between a MIPS eligible clinician or group and a health IT vendor, QCDR, or qualified registry for data submission for CPIA as well as other performance data submitted outside of the CPIA performance category could be contained in a single agreement, minimizing the burden on the MIPS eligible clinician or group. See section II.E.9 for additional details.

We propose to use the administrative claims method, if technically feasible, only to supplement CPIA submissions. For example, if technically feasible, MIPS eligible clinicians or groups, using the telehealth modifier GT, could get automatic credit for this activity. We request comments on these proposals.

(b) Weighted Scoring

While we considered both equal and differentially weighted scoring in this performance category, the statute requires a differentially weighted scoring model by requiring 100 percent of the potential score in the CPIA performance category for patient-centered medical home participants, and a minimum 50 percent score for APM participants. For additional activities in this category, we propose at § 414.1380 a differentially weighted model for the CPIA performance category with two categories: Medium and high. The justification for these two weights is to provide flexible scoring due to the undefined nature of activities (that is, CPIA standards are not nationally recognized and there is no entity for CPIA that serves the same function as the National Quality Forum does for quality measures). CPIAs are weighted as high based on alignment with CMS national priorities and programs such as the Quality Innovation Network-Quality Improvement Organization (QIN/QIO) or the Comprehensive Primary Care Initiative which recognizes specific activities related to expanded access and integrated behavioral health as important. Programs that require performance of multiple activities such as participation in the Transforming Clinical Practice Initiative, seeing new and follow-up Medicaid patients in a timely manner in the provider's State Medicaid Program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) were weighted as high.

The statute references patient-centered medical homes as achieving the highest score for the MIPS program. MIPS eligible clinicians or groups may use that to guide them in the criteria or factors that should be taken into consideration to determine whether to weight an activity medium or high on comments for this proposal. We request comments on this proposal, including criteria or factors we should take into consideration to determine whether to weight an activity medium or high.

(c) Submission Criteria

We propose at § 414.1380 to set the CPIA submission criteria under MIPS, in order to achieve the highest potential score of 100 percent, at three high-weighted CPIAs (20 points each) or six medium-weighted CPIAs (10 points each), or some combination of high and medium-weighted CPIAs to achieve a total of 60 points for MIPS eligible clinicians participating as individuals or as groups (refer to Table H of the Appendices for CPIAs and weights). MIPS eligible clinicians or groups that select less than the designated number of CPIAs will receive partial credit based on the weighting of the CPIA selected. To achieve a 50 percent score, one high-weighted and one medium-weighted CPIA or three medium-weighted CPIAs are required for these MIPS eligible clinicians or groups.

Exceptions to the above apply for: MIPS small groups (consisting of 15 or fewer clinicians), MIPS eligible clinicians and groups located in rural areas, MIPS eligible clinicians and groups that are located in geographic HPSAs, non-patient-facing MIPS eligible clinicians or groups or MIPS eligible clinicians, or groups that participate in an APM and/or a patient-centered medical home submitting in MIPS.

For MIPS eligible clinicians and groups that are small, located in rural areas or geographic HPSAs, or non-patient-facing MIPS eligible clinicians or groups, in order to achieve the highest score of 100 percent, two CPIAs are required (either medium or high).

For MIPS eligible clinicians or groups that are small, located in rural areas, located in HPSAs, or non-patient-facing MIPS eligible clinicians or groups, in order to achieve a 50 percent score, one CPIA is required (either medium or high).

MIPS eligible clinicians or groups that participate in APMs are considered eligible to participate under the CPIA performance category unless they are participating in an Advanced APM and they have met the Qualifying APM Participant (QP) thresholds or are Partial QPs that elect not to report information. A MIPS eligible clinician or group that is participating in an APM and participating under the CPIA performance category will receive 50 percent of the total CPIA score (30 points) just through their APM participation. These are MIPS eligible clinicians or groups that CMS identifies as participating in APMs for MIPS and may participate under the CPIA performance category. To achieve 100 percent of the total CPIA score, MIPS eligible clinicians or groups will need to identify that they participate in an alternative payment model (30 points) and also select additional CPIAs for an additional 30 points to reach the 60 point CPIA highest score.

For further description of MIPS eligible clinicians or groups that are required to report to MIPS under the APM scoring standard and their CPIA scoring requirements, we refer readers to section II.E.5.h. For all other MIPS eligible clinicians or groups participating in APMs that would report to MIPS, this section applies and we also refer readers to the scoring requirements for these MIPS eligible clinicians or groups in section II.E.6.

Since we cannot measure variable performance within a single CPIA, we propose at § 414.1380 to compare the CPIA points associated with the reported activities against the highest number of points that are achievable under the CPIA performance category which is 60 points. We propose that the highest potential score of 100 percent can be achieved by selecting a number of activities that will add up to 60 points. MIPS eligible clinicians and groups, including those that are participating as an APM, and all those that select activities under the CPIA performance category can achieve the highest potential score of 60 points by selecting activities that are equal to the 60-point maximum. We refer readers to scoring section II.E.6 for additional rationale for using 60 points for the first year.

If a MIPS eligible clinician or group reports only one CPIA, we will score that activity accordingly, as 10 points for a medium-level activity or 20 points for a high-level activity. If a MIPS eligible clinician or group reports no CPIAs, then the MIPS eligible clinician or group would receive a zero score for the CPIA performance category. We believe this proposal allows us to capture variation in the total CPIAs reported.

In addition, we believe these are reasonable criteria for MIPS eligible clinicians or groups to accomplish within the first year for three reasons: (1) In response to several stakeholder MIPS and APMs RFI comments, we are not recommending a minimum number of hours for performance of an activity; (2) we are offering a broad list of activities from which MIPS eligible clinicians or groups may select; and (3) also in response to MIPS and APMs RFI comments, we are proposing that an activity must be performed for at least 90 days during the performance period for CPIA credit. We intend to reassess this requirement threshold in future years. We do not believe it is appropriate to require a determined number of activities within a specific subcategory at this time. This proposal aligns with the requirements in section 1848(q)(2)(C)(iii) of the Act that states MIPS eligible clinicians or groups are not required to perform activities in each subcategory.

Lastly, we recognize that working with a QCDR could allow a MIPS eligible clinician or group to meet the measure and activity criteria for multiple CPIAs. For the first year of MIPS, there are several CPIAs in the inventory that incorporate QCDR participation. Each activity must be selected and achieved separately for the first year of MIPS. A MIPS eligible clinician or group cannot receive credit for multiple activities just by selecting one activity that includes participation in a QCDR. As the CPIA inventory expands over time we are interested in receiving comments on what restrictions, if any, should be placed around CPIA measures and activities that incorporate QCDR participation.

(d) Required Period of Time for Performing an Activity

We propose § 414.1360 that MIPS eligible clinicians or groups must perform CPIAs for at least 90 days during the performance period for CPIA credit. We understand there are some activities that are ongoing whereas others may be episodic. We considered setting the threshold for the minimum time required for performing an activity to longer periods up to a full calendar year. However, after researching several organizations we believe a minimum of 90 days is a reasonable amount of time. Two illustrative examples of organizations that used 90 days as a window for reviewing clinical practice improvements include practice improvement activities undertaken by anesthesiologists, as detailed in a study describing anesthesiologists' practice improvements as part of the Maintenance of Certification in Anesthesiology Program requiring a 90-day report back period,[10] [11] and a large Veteran's Administration health care program that set a 90-day window for reviewing improvements in the management of opioid dispensing.[12]

Additional clarification for how some activities meet the 90-day rule or if additional time is required are reflected in the description of that activity in Table H of the Appendices. In addition we propose that activities, where applicable, may be continuing (that is, could have started prior to the performance period and are continuing) or be adopted in the performance period as long as an activity is being performed for at least 90 days during the performance period.

We anticipate in future years that extended CPIA time periods will be needed for certain activities. We will monitor the time period requirement to asses if allowing for extended time requirements may enhance the value associated with generating more effective outcomes, or conversely, the extended time may reveal that more time has little or no value added for certain activities when associated with desired outcomes. We request comments on this proposal.

(4) Application of CPIA to Non-Patient-Facing MIPS Eligible Clinicians and Groups

We understand that non-patient-facing MIPS eligible clinicians and groups may have a limited number of measures and activities to report. Therefore, we propose at § 414.1360 allowing non-patient-facing MIPS eligible clinicians and groups to report on a minimum of one activity to achieve partial credit or two activities to achieve full credit to meet the CPIA submission criteria. These non-patient-facing MIPS eligible clinicians and groups receive partial or full credit for submitting one or two activities irrespective of any type of weighting, medium or high (for example, two medium activities will qualify for full credit). For scoring purposes, non-patient-facing MIPS eligible clinicians or groups receive 30 points per activity, regardless of whether the activity is medium or high. For example, one high activity and one medium activity could be selected to receive 60 points. Similarly, two medium activities could also be selected to receive 60 points.

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[10] Steadman R.H, Burden AR, Huang, YM, Gaba DM, et. al, Practice improvements based on participation in simulation for the maintenance of certification in anesthesiology program. Anesthesiology. 2015;122;1154–69.

[11] ABMS cite.

[12] Westanmo A, Marshall P, Jones E, Burns K, Krebs EE., Opioid Dose Reduction in a VA Health Care System—Implementation of a Primary Care Population-Level Initiative. Pain Med. 2015;16(5);1019–26.

We anticipate the number of activities for non-patient-facing MIPS eligible clinicians or groups will increase in future years as we gather more data on the feasibility of performing CPIAs. As part of the process for identifying activities, we consulted with several organizations that represent a cross-section of non-patient-facing MIPS eligible clinicians and groups. An illustrative example of those consulted with include organizations that represent cardiologists involved in nuclear medicine, nephrologists who serve only in a consulting role to other providers, or pathologists who, while they typically function as a team, have different members that perform different roles within their specialty that are primarily non-patient-facing.

In the course of those discussions these organizations identified CPIAs they believed would be applicable. Comments on activities appropriate for non-patient-facing MIPS eligible clinicians or groups are reflected in the proposed CPIA Inventory across multiple subcategories. For example, several of these organizations suggested consideration for Appropriate Use Criteria (AUC). As a result, we have incorporated AUC into some of the activities. We encourage MIPS eligible clinicians or groups who are already required to use AUC (for example, for advanced imaging) to report a CPIA other than one related to appropriate use. Another example, under Patient Safety and Practice Assessment, is the implementation of an antibiotic stewardship program that measures the appropriate use of antibiotics for several different conditions (Upper Respiratory Infection (URI) treatment in children, diagnosis of pharyngitis, bronchitis treatment in adults) according to clinical guidelines for diagnostics and therapeutics. In addition, we request comments on what activities would be appropriate for non-patient-facing MIPS eligible clinicians or groups to add to the CPIA Inventory in the future. We request comments on this proposal.

(5) Special Consideration for Small, Rural, or Health Professional Shortage Areas Practices

As noted previously in this proposed rule, section 1848(q)(2)(B)(iii) of the Act requires the Secretary, in establishing CPIAs, to give consideration to small practices (15 or fewer clinicians) and practices located in rural areas (proposed definition at § 414.1305) and in geographic based HPSAs as designated under section 332(a)(1)(A) of the Public Health Service Act. In the MIPS and APMs RFI, we requested comments on how CPIAs should be applied to MIPS eligible clinicians or groups in small practices, in rural areas, and geographic HPSAs: If a lower performance requirement threshold or different measures should be established that will better allow those MIPS eligible clinicians or groups to perform well in this performance category, what methods should be leveraged to appropriately identify these practices, and what best practices should be considered to develop flexible and adaptable CPIAs based on the needs of the community and its population.

We engaged high performing organizations, including several rural health clinics with 15 or fewer clinicians that are designated as geographic HPSAs, to provide feedback on relevant QIN/QIO activities based on their specific circumstances. Some examples provided include participation in implementation of self-management programs such as for diabetes, and early use of telemedicine, as in the one case for a top performing multi-specialty rural practice that covers 20,000 people over a 25,000-mile radius in a rural area of North Dakota. Comments on activities appropriate for MIPS eligible clinicians or groups located in rural areas or practices that are designated as geographic HPSAs are reflected in the proposed CPIA Inventory across multiple subcategories.

Based on the review of comments and listening sessions, we propose at § 414.1360 to accommodate small practices and practices located in rural areas, or geographic HPSAs for the CPIA performance category by allowing MIPS eligible clinicians or groups to submit a minimum of one activity to achieve partial credit or two activities to achieve full credit. These MIPS eligible clinicians or groups receive partial or full credit for submitting two activities of any type of weighting (for example, two medium activities will qualify for full credit). We anticipate the requirement on the number of activities for small practices and practices located in rural areas, or practices in geographic HPSAs will increase in future years as we gather more data on the feasibility of small practices and practices located in rural areas and practices located in geographic HPSAs to perform CPIAs. Therefore, we request comments on what activities would be appropriate for these practices for the CPIA Inventory in future years. We request comments on this proposal.

(6) CPIA Subcategories

Section 1848(q)(2)(B)(iii) of the Act provides that the CPIA performance category must include at least the subcategories listed below. The statute also provides the Secretary discretion to specify additional subcategories for the CPIA performance category, which have also been included below.

- Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
- Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.
- Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other MIPS eligible clinicians or groups, and use of remote monitoring or telehealth.
- Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
- Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.
- Participation in an APM, as defined in section 1833(z)(3)(C) of the Act.

In the MIPS and APMs RFI, we requested recommendations on the inclusion of the following five potential new subcategories:

- Promoting Health Equity and Continuity, including (a) serving Medicaid beneficiaries, including individuals dually eligible for Medicaid and Medicare, (b) accepting new Medicaid beneficiaries, (c) participating in the network of plans in the Federally Facilitated Marketplace or state exchanges, and (d) maintaining adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) to provide comprehensive care for patients with disabilities.
- Social and Community Involvement, such as measuring

completed referrals to community and social services or evidence of partnerships and collaboration with the community and social services.

- Achieving Health Equity, as its own performance category or as a multiplier where the achievement of high quality in traditional areas is rewarded at a more favorable rate for MIPS eligible clinicians or groups that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.
- Emergency preparedness and response, such as measuring MIPS eligible clinician or group participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty military MIPS eligible clinician or group activities, and measuring MIPS eligible clinician or group volunteer participation in domestic or international humanitarian medical relief work.
- Integration of primary care and behavioral health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; or cross-training of MIPS eligible clinicians or groups participating in integrated care. This subcategory also includes integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

We recognize that quality improvement is a critical aspect of improving the health of individuals and the health care delivery system overall. We also recognize that this will be the first time MIPS eligible clinicians or groups will be measured on the quality improvement work on a national scale. We have approached the CPIA performance category with these principles in mind along with the overarching principle for the MIPS program that we are building a process that will have increasingly more stringent requirements over time.

Therefore, for the first year of MIPS, we propose at § 414.1365 that the CPIA performance category include the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. In addition, we propose at § 414.1365 adding the following subcategories: "Achieving Health Equity", "Integrated Behavioral and Mental Health", and "Emergency Preparedness and Response." In response to multiple MIPS and APMs RFI comments requesting the inclusion of "Achieving Health Equity," we are proposing to include this subcategory because: (1) It is important and may require targeted effort to achieve and so should be recognized when accomplished; (2) supports our national priorities and programs, such as Reducing Health Disparities; and (3) encourages "use of plans, strategies, and practices that consider the social determinants that may contribute to poor health outcomes." (CMS, Quality Innovation Network Quality Improvement Organization Scope of Work: Excellence in Operations and Quality Improvement, 2014).

Similarly, MIPS and APMs RFI comments strongly supported the inclusion of the subcategory of "Integrated Behavioral and Mental Health", citing that "statistics show 50 percent of all behavioral health disorders are being treated by primary care and behavioral health integration." Additionally, according to MIPS and APMs RFI comments, behavioral health integration with primary care is already being implemented in numerous locations throughout the country. The third additional subcategory we propose to include is "Emergency Preparedness and Response," based on MIPS and APMs RFI comments that encouraged us to consider this subcategory to help ensure that practices remain open during disaster and emergency situations and support emergency response teams as needed. Additionally, commenters were able to provide a sufficient number of recommended activities (that is, more than one) that could be included in the CPIA Inventory in all of these proposed subcategories and the subcategories included under section 1848(q)(2)(B)(iii) of the Act.

We also seek public comments on two additional subcategories for future consideration:

- Promoting Health Equity and Continuity, including (a) serving Medicaid beneficiaries, including individuals dually eligible for Medicaid and Medicare, (b) accepting new Medicaid beneficiaries, (c) participating in the network of plans in the Federally Facilitated Marketplace or state exchanges, and (d) maintaining adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) to provide comprehensive care for patients with disabilities; and
- Social and Community Involvement, such as measuring completed referrals to community and social services or evidence of partnerships and collaboration with community and social services.

For these two subcategories, we are requesting activities that can demonstrate some improvement over time and go beyond current practice expectations. For example, maintaining existing medical equipment would not qualify for a CPIA, but implementing some improved clinical workflow processes that reduce wait times for patients with disabilities or improve coordination of care including activities that regularly provide additional assistance to find other care needed for patients with disabilities, would be some examples of activities that could show improvement in clinical practice over time.

We request comments on these proposals.

(7) CPIA Inventory

To implement the MIPS program, we are required to create an inventory of CPIAs. Consistent with our MIPS strategic goals, we believe it is important to create a broad list of activities that can be used by multiple practice types to demonstrate CPIAs and activities that may lend themselves to being measured for improvement in future years.

We took several steps to ensure the initial CPIA Inventory is inclusive of activities in line with the statutory intent. We had numerous interviews with highly performing organizations of all sizes, conducted an environmental scan to identify existing models, activities, or measures that met all or part of the CPIA category, including the patient centered medical homes, the Transforming Clinical Practice Initiative (TCPI), Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 70886) and the comments received in response to the MIPS and APMs RFI regarding the CPIA performance category. The CPIA Inventory was compiled as a result of the stakeholder input, an environmental scan, MIPS and MIPS and APMs RFI comments, and subsequent working sessions with AHRQ and ONC and additional communications with CDC, SAMHSA and HRSA.

Based on the above discussions we established guidelines for CPIA inclusion based on one or more of the following criteria (in any order):

- Relevance to an existing CPIA subcategory (or a proposed new subcategory);

- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Representative of activities that multiple MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small (15 or fewer clinicians) practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- CMS is able to validate the activity; or
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes.

Activities that overlap with other performance categories were excluded unless there was a strong policy rationale to include it in the CPIA Inventory. We propose to use the CPIA Inventory for the first year of MIPS, as provided in Table H of the Appendices. For further description of how MIPS eligible clinicians or groups will be designated to submit to MIPS for CPIA, we refer readers to section II.E.6.h. For all other MIPS eligible clinicians or groups participating in APMs that would report to MIPS, this section applies and we also refer readers to the scoring requirements for these MIPS eligible clinicians or groups in section II.E.5. of this proposed rule.

We request comments on the inventory and welcome suggestions for CPIAs for future years as well.

(a) CMS Study on CPIA and Measurement

(1) Study Purpose

From our experience under the PQRS, VM, and Medicare EHR Incentive programs we have discovered that many providers have errors within their data sets, as well as issues understanding the data that corresponds to their selected quality measures. To help better understand the current processes and limitations, we propose to conduct a study on CPIAs and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures. The study will allow a limited number of selected MIPS eligible clinicians and groups to receive full credit (60 points) for the CPIA category.

The lessons learned in this study on practice improvement and measurement may or may not influence changes to future MIPS data submission requirements. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring:

- A more data driven approach to quality measurement.
- Measure selection unconstrained with a CEHRT program or system.
- Improving data quality submitted to CMS.
- Enabling CMS get data more frequently and provide feedback more often.

(2) Study Participation Credit and Requirements

Eligible clinicians and groups in the CMS study on practice improvement and measurement will receive full credit for the CPIA category of MIPS after successfully electing, participating and submitting data to CMS. Based on feedback and surveys from MIPS eligible clinicians, study measurement data will be made available to CMS throughout the study on at least a quarterly basis unless the MIPS eligible clinician or group agrees to submit data on a more frequent basis. Participants will be required to attend a monthly focus group to share lessons learned along with providing survey feedback to monitor effectiveness. The focus group will also include providing visual displays of data, workflows, and best practices to be shared amongst the participants to obtain feedback and make further improvements. The monthly focus groups will be used to learn from the practices on how to be more agile as we test new ways of measure recording and workflow.

For the 2017 performance period, the participating MIPS eligible clinicians or groups would submit their data and workflows for a minimum of three MIPS clinical quality measures that are relevant and prioritized by their practice. One of the measures must be an outcome measure, and one must be a patient experience measure. The participating MIPS eligible clinicians could elect to report on more measures as this would provide more options from which to select in subsequent years for purposes of measuring improvement.

If MIPS eligible clinicians or groups calculate the measures working with a QCDR, qualified registry, or CMS-approved third party intermediary, CMS will use the same data validation process described in section II.E.8.e. CMS will only collect the numerator and denominator for the measures selected for the overall population, all patients/all payers. This will enable the practices to build the measures based on what is important for their area of practice while increasing the quality of care.

In future years, participating MIPS eligible clinicians or groups would select three of the measures for which they have baseline data from the 2017 performance period to compare against later performance years. Participants electing to continue in future years will be afforded the opportunity opt-in or opt-out following the successful submission of data to CMS. The first opportunity to continue in the study will be at the end of the 2017 performance period. Eligible clinicians who elect to join the study but fail to participate and/or fail to successfully submit the data required will be removed from the study. Unsuccessful study participants will then be subject to the full requirements for the CPIA category.

(3) Study Participation Eligibility

Participation will be open to a limited number of MIPS eligible clinicians in rural settings and non-rural settings. A rural area is defined at § 414.1305 and a non-rural area would be any MIPS eligible clinicians or groups not included as part of the rural definition. This test will be open to include up to 10 non-rural individual MIPS eligible clinicians or groups of less than three non-rural MIPS eligible clinician's, 10 rural individual MIPS eligible clinicians or groups of less than three rural MIPS eligible clinician's, 10 groups of three to eight MIPS eligible clinicians, five groups of nine to twenty MIPS eligible clinicians, three groups of twenty-one to one hundred MIPS eligible clinicians, two groups of greater than 100 MIPS eligible clinicians, and two specialist groups of MIPS eligible clinicians. Eligible clinicians and groups will need to sign up from January 1, 2017, to January 31, 2017. The sign up process will utilize this web-based interface—*http://oncprojecttracking.org/*. Participants will be approved on a first come first served basis and must meet all the required criteria.

We request comment on the study and welcome suggestions on future study topics.

(8) CPIA Policies for Future Years of the MIPS Program

(a) Proposed Approach for Identifying New Subcategories and New Activities

We propose, for future years of, MIPS, to consider the addition of a new subcategory or activity to the CPIA

Inventory only when the following criteria are met:

- The new subcategory represents an area that could highlight improved beneficiary health outcomes, patient engagement and safety based on evidence.
- The new subcategory has a designated number of activities that meet the criteria for a CPIA activity and cannot be classified under the existing subcategories.
- Newly identified subcategories would contribute to improvement in patient care practices or improvement in performance on quality measures and resource use performance categories.

In future years, MIPS eligible clinicians or groups will have an opportunity to nominate additional subcategories, along with activities associated with each of those subcategories that are based on criteria specified for these activities, as discussed above.

We request comments on this proposal.

(b) Request for Comments on Call for Measures and Activities Process for Adding New Activities and New Subcategories

We plan to develop a call for measures and activities process for future years of MIPS, where MIPS eligible clinicians or groups and other relevant stakeholders may recommend activities for potential inclusion in the CPIA Inventory. As part of the process, MIPS eligible clinicians or groups would be able to nominate additional activities that we could consider adding to the CPIA Inventory. The MIPS eligible clinician or group or relevant stakeholder would be able to provide an explanation of how the activity meets all the criteria we have identified. This nomination and acceptance process would, to the best extent possible, parallel the annual call for measures process already conducted by CMS for quality measures. The final CPIA Inventory for the performance year would be published in accordance with the overall MIPS rulemaking timeline and program. In addition, in future years we anticipate developing a process and establishing criteria to remove or add new activities to CPIA.

Additionally, prospective activities that are submitted through a QCDR could also be included as part of a beta-test process that may be instrumental for future years to determine whether that activity should be included in the CPIA Inventory based on specific criteria noted above. MIPS eligible clinicians or groups and groups that use QCDRs to capture data associated with an activity, for example the frequency in administering depression screening and a follow-up plan, may be asked to voluntarily submit that same data in year 2 to begin identifying a baseline for improvement for subsequent year analysis. This is not intended to require any MIPS eligible clinician or group to submit CPIAs only via QCDR from one year to the next or to require the same activity from one year to the next. Participation in doing so, however, can help to identify how activities can contribute to improve outcomes. This data submission process will be considered part of a beta-test to: (1) Determine if the activity is being regularly conducted and effectively executed and (2) if the activity warrants continued inclusion on the CPIA Inventory. The data will help capture baseline information to begin measuring improvement and inform the Secretary of the likelihood that the activity would result in improved outcomes. If an activity is submitted and reported by a QCDR, it would be reviewed by CMS for final inclusion in the CPIA Inventory the following year, even if these activities are not submitted through the future call for measures and activities process. We intend, in future performance years, to begin measuring CPIA data points for all eligible clinicians and to award scores based on performance and improvement. We solicit comment on how best to collect such CPIA data and factor it into future scoring under MIPS.

We request comments on this approach and on any other considerations we should take into account when developing this type of approach for future rulemaking.

(c) Request for Comments on Use of QCDRs for Identification and Tracking of Future Activities

In future years, we expect to learn more about CPIAs and how the inclusion of additional measures and activities captured by QCDRs could enhance the ability of MIPS eligible clinicians or groups to capture and report on more meaningful activities. This is especially true for specialty groups. In the future, we may propose use of QCDRs for identification and acceptance of additional measures and activities which is in alignment with section 1848(q)(1)(E) of the Act which encourages the use of QCDRs, as well as under section 1848(q)(2)(B)(iii)(II) of the Act related to the population management subcategory. We recognize, through the MIPS and APMs RFI comments and interviews with organizations that represent non-patient-facing MIPS eligible clinicians or groups and specialty groups that QCDRs may provide for a more diverse set of measures and activities under CPIA than are possible to list under the current CPIA Inventory. This diverse set of measures and activities, which we can validate, affords specialty practices additional opportunity to report on more meaningful activities in future years. QCDRs may also provide the opportunity for longer-term data collection processes which will be needed for future year submission on improvement, in addition to achievement. Use of QCDRs also supports ongoing performance feedback and allows for implementation of continuous process improvements. We believe that for future years, QCDRs will be allowed to define specific CPIAs for specialty and non-patient-facing MIPS eligible clinicians or groups through the already-established QCDR approval process for measures and activities. We request comments on this approach.

g. Advancing Care Information Performance Category

(1) Background and Relationship to Prior Programs

(a) Background

The American Recovery and Reinvestment Act of 2009 (ARRA), which included the Health Information Technology for Economic and Clinical Health Act (HITECH Act), amended Titles XVIII and XIX of the Act to authorize incentive payments and Medicare payment adjustments for EPs to promote the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o) of the Act provides the statutory basis for the Medicare incentive payments made to meaningful EHR users. Section 1848(a)(7) of the Act also establishes downward payment adjustments, beginning with calendar year (CY) 2015, for EPs who are not meaningful users of certified EHR technology for certain associated EHR reporting periods. (For a more detailed explanation of the statutory basis for the Medicare and Medicaid EHR Incentive Programs, see the July 28, 2010 Stage 1 final rule titled, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule" (75 FR 44316 through 44317).)

A primary policy goal of the EHR Incentive Program is to encourage and promote the adoption and use of certified EHR technology among Medicare and Medicaid health care providers to help drive the industry as a whole toward the use of certified EHR technology. As described in the final rule titled "Medicare and Medicaid

Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017" (Hereinafter referred to as the "2015 EHR Incentive Programs Final Rule") (80 FR 62769), the HITECH Act outlined several foundational requirements for meaningful use and for EHR technology. CMS and ONC have subsequently outlined a number of key policy goals which are reflected in the current objectives and measures of the program and the related certification requirements (80 FR 62790). Current Medicare EP performance on these key goals is varied, with EPs demonstrating high performance on some objectives while others represent a greater challenge.

(b) MACRA Changes

Section 1848(q)(2)(A) of the Act, as added by section 101(c) of the MACRA, includes the meaningful use of certified EHR technology as a performance category under the MIPS, referred to in this proposed rule as the advancing care information performance category, which will be reported by MIPS eligible clinicians as part of the overall MIPS program. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories shall be used in determining the MIPS CPS for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the advancing care information performance category. This includes MIPS eligible clinicians who were not previously eligible for the EHR Incentive Program incentive payments under section 1848(o) of the Act or subject to the EHR Incentive Program payment adjustments under section 1848(a)(7) of the Act, such as physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and hospital-based EPs (as defined in section 1848(o)(1)(C)(ii) of the Act). Understanding that these MIPS eligible clinicians may not have prior experience with certified EHR technology and the objectives and measures under the EHR Incentive Program, we have proposed a scoring methodology within the advancing care information performance category that provides flexibility for MIPS eligible clinicians from early adoption of certified EHR technology through advanced use of health IT. We note that in section II.e.5.g.8.a of this proposed rule, we have also proposed to reweight the advancing care information performance category to zero in the MIPS composite performance score for certain hospital-based and other MIPS eligible clinicians where the measures proposed for this performance category may not be available or applicable to these types of MIPS eligible clinicians.

(c) Considerations in Defining Advancing Care Information Performance Category

In implementing MIPS, we intend to develop the requirements for the advancing care Information performance category to continue supporting the foundational objectives of the HITECH Act, and to encourage continued progress on key uses such as health information exchange and patient engagement. These more challenging objectives are essential to leveraging certified EHR technology to improve care coordination and they represent the greatest potential for improvement and for significant impact on delivery system reform in the context of MIPS quality reporting.

In developing the requirements and structure for the advancing care information performance category, we considered several approaches for establishing a framework that would naturally integrate with the other MIPS performance categories. We considered historical performance on the EHR Incentive Program objectives and measures, feedback received through public comment, and the long term goals for delivery system reform and quality improvement strategies.

One approach we considered would be to maintain the current structure of the Medicare EHR Incentive Program and award full points for the advancing care information performance category for meeting all of the objectives and measures finalized in the 2015 EHR Incentive Programs final rule, and award zero points for failing to meet all of these requirements. This method would be consistent with the current EHR Incentive Program and is based on objectives and measures already established in rulemaking. However, we considered and dismissed this approach as it would not allow flexibility for MIPS eligible clinicians and would not allow CMS to effectively measure performance for MIPS eligible clinicians in the advancing care information performance category who have taken incremental steps toward the use of certified EHR technology, or to recognize exceptional performance for MIPS eligible clinicians who have excelled in any one area. This is particularly important as many MIPS eligible clinicians may not have had past experience relevant to the advancing care information performance category and use of EHR technology because they were not previously eligible to participate in the Medicare EHR Incentive Program. This approach also does not allow for differentiation among the objectives and measures that have high adoption and those where there is potential for continued advancement and growth.

We subsequently considered several methods which would allow for more flexibility and provide CMS the opportunity to recognize partial or exceptional performance among MIPS eligible clinicians for the measures under the advancing care information performance category. We decided to design a framework that would allow for flexibility and multiple paths to achievement under this category while recognizing MIPS eligible clinicians' efforts at all levels. Part of this framework requires moving away from the concept of requiring a single threshold for a measure, and instead incentivizes continuous improvement, and recognizes onboarding efforts among late adopters and MIPS eligible clinicians facing continued challenges in full implementation of certified EHR technology in their practice.

(2) Advancing Care Information Performance Category Within MIPS

In defining the advancing care information performance category for the MIPS, we considered stakeholder feedback and lessons learned from our experience with the Medicare EHR Incentive Program. Specifically, we considered feedback from the Stage 1 (75 FR 44313) and Stage 2 (77 FR 53967) EHR Incentive Program rules, and the 2015 EHR Incentive Programs final rule (80 FR 62769), as well as comments received from the MIPS and APMs RFI (80 FR 59102). We have learned from this feedback that clinicians desire flexibility to focus on health IT implementation that is right for their practice. We have also learned that updating software, training staff and changing practice workflows to accommodate new technology can take time, and that clinicians need time and flexibility to focus on the health IT activities that are most relevant to their patient population. Clinicians also desire consistent timelines and reporting requirements in order to simplify and streamline the reporting process. Recognizing this, we have worked to align the advancing care information performance category with the other MIPS performance categories, which would streamline reporting requirements, timelines and measures in an effort to reduce burden on MIPS eligible clinicians.

The implementation of the advancing care information performance category is an important opportunity to increase clinician and patient engagement, improve the use of health IT to achieve better patient outcomes, and continue to meet the vision of enhancing the use of certified EHR technology as defined under the HITECH Act. As discussed later in this section, we are proposing in section II.E.5.g.6.a. new flexibility in how we would assess MIPS eligible clinician performance for the advancing care information performance category. We propose to emphasize performance in the objectives and measures that are the most critical and would lead to the most improvement in the use of health IT and health care quality. We intend to promote innovation so that technology can be interconnected easily and securely, and data can be accessed and directed where and when it is needed to support patient care. These objectives include Patient Electronic Access, Coordination of Care Through Patient Engagement and Health Information Exchange, which are essential to leveraging certified EHR technology to improve care. At the same time, we propose to eliminate reporting on objectives and measures in which the vast majority of clinicians already achieve high performance—which would reduce burden, encourage greater participation and direct MIPS eligible clinicians' attention to higher-impact measures. Our proposal balances program participation with rewarding performance on high-impact objectives and measures, which we believe would make the overall program stronger and further the goals of the HITECH Act.

(a) Advancing the Goals of the HITECH Act in MIPS

Section 1848(o)(2)(A) of the Act requires that the Secretary seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use. In implementing MIPS and the advancing care information performance category, we seek to improve and encourage the use of certified EHR technology over time by adopting a new, more flexible scoring methodology, as discussed in section II.E.5.g.6. of this proposed rule, that would more effectively allow MIPS eligible clinicians to reach the goals of the HITECH Act, and would allow MIPS eligible clinicians to use EHR technology in a manner more relevant to their practice. This new, more flexible scoring methodology puts a greater focus on Patient Electronic Access, Coordination of Care Through Patient Engagement, and Health Information Exchange—objectives we believe are essential to leveraging certified EHR technology to improve care by engaging patients and furthering interoperability. This methodology would also de-emphasize objectives in which clinicians have historically achieved high performance with median performance rates of over 90 percent for the last 2 years. We believe shifting focus away from these objectives would reduce burden, encourage greater participation, and direct attention to other objectives and measures which require more attention. Through this flexibility, MIPS eligible clinicians would be incentivized to focus on those aspects of certified EHR technology that are most relevant to their practice, which we believe would lead to improvements in health care quality.

We also seek to increase the adoption and use of certified EHR technology by incorporating such technology into the other MIPS performance categories. For example, in section II.6.a.2.f. of this proposed rule, we are proposing to incentivize electronic reporting by awarding a bonus point for submitting quality measure data using certified EHR technology. Additionally, in section II.E.5.f. of this proposed rule, we have aligned some of the activities under the CPIA performance category such as Care Coordination, Beneficiary Engagement and Achieving Health Equity with a focus on enhancing the use of certified EHR technology. We believe this approach would strengthen the adoption and use of EHR systems and program participation consistent with the provisions of section 1848(o)(2)(A) of the Act.

(b) Future Considerations

We note that the increased flexibility and removal of previously established thresholds for reporting, as proposed in this section of this proposed rule, may appear to be a lower standard than what previously existed in the Medicare EHR Incentive Program. In reality, this restructuring of program requirements is geared toward increasing participation and EHR adoption. We believe this is the most effective way to encourage the adoption of certified EHR technology, and introduce new MIPS eligible clinicians to the use of EHR technology and health IT overall.

We will continue to review and evaluate MIPS eligible clinician performance in the advancing care information performance category, and will consider evolutions in health IT over time as it relates to this performance category. Based on our ongoing evaluation, we expect to adopt changes to the scoring methodology for the advancing care information performance category to ensure the efficacy of the program and to ensure increased value for MIPS eligible clinicians, as well as to adopt more stringent measures of meaningful use as required by section 1848(o)(2)(A) of the Act.

Potential changes may include establishing benchmarks for MIPS eligible clinician performance on the advancing care information performance category measures, and using these benchmarks as a baseline or threshold for future reporting. This may include scoring for performance improvement over time and the potential to reevaluate the efficacy of measures based on these analyses. For example, in future years we may use a MIPS eligible clinician's prior performance on the advancing care information performance category measures as comparison for the subsequent year's performance category score, or compare a MIPS eligible clinician's performance category score to peer groups to measure their improvement and determine a performance category score based on improvement over those benchmarks or peer group comparisons. This type of approach would drive continuous improvement over time through the adoption of more stringent performance standards for the advancing care information performance category measures.

We are committed to continual review, improvement and increased stringency of the advancing care information performance category measures as directed under section 1848(o)(2)(A) of the Act both for the purposes of ensuring program efficacy as well as ensuring value for the MIPS eligible clinicians reporting the advancing care information performance category measures. We seek comment on further methods to increase the stringency of the advancing care information performance category measures in the future.

We additionally seek comment on the concept of a holistic approach to health IT—one that we believe is similar to the concept of outcome measures in the quality performance category in the sense that MIPS eligible clinicians could potentially be measured more directly on how the use of health IT contributes to the overall health of their patients. Under this concept, MIPS eligible clinicians would be able to track certain use cases or patient outcomes to tie patient health outcomes with the use of health IT.

We believe this approach would allow us to directly link health IT adoption and use to patient outcomes, moving

MIPS beyond the measurement of EHR adoption and process measurement and into a more patient-focused health IT program. From comments and feedback we have received from the health care provider community, we understand that this type of approach would be a welcome enhancement to the measurement of health IT. At this time, we recognize that technology and measurement for this type of program is currently unavailable. We seek comment on what this type of measurement would look like under MIPS, including the type of measures that would be needed within the advancing care information performance category and the other performance categories to measure this type of outcome, what functionalities with certified EHR technology would be needed, and how such an approach could be implemented.

(3) Clinical Quality Measurement

Section 1848(o)(2)(A)(iii) of the Act requires the reporting of clinical quality measures (CQMs) using certified EHR technology. Section 1848(q)(5)(B)(ii)(II) provides that under the methodology for assessing the total performance of each MIPS eligible clinician, the Secretary shall, with respect to a performance period for a year, for which a MIPS eligible clinician reports applicable measures under the quality performance category through the use of certified EHR technology, treat the MIPS eligible clinician as satisfying the CQMs reporting requirement under section 1848(o)(2)(A)(iii) of the Act for such year. We note that in the context and overall structure of MIPS, the quality performance category allows for a greater focus on patient-centered measurement, and multiple pathways for MIPS eligible clinicians to report their quality measure data. Therefore, we are not proposing separate requirements for clinical quality measure reporting within the advancing care information performance category and instead would require submission of quality data for measures specified for the quality performance category, in which we encourage reporting of CQMs with data captured in certified EHR technology. We refer readers to section II.E.5.a of this proposed rule for discussion of reporting of CQMs with data captured in certified EHR technology under the quality performance category.

(4) Performance Period Definition for Advancing Care Information Performance Category

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 proposed rule, we proposed to eliminate the 90-day EHR reporting period beginning in 2017 for EPs who had not previously demonstrated meaningful use, with a limited exception for the Medicaid EHR Incentive Program (80 FR 16739–16740, 16774–16775). We received many comments from respondents stating their preference for maintaining the 90-day EHR reporting period to allow first time participants to avoid payment adjustments. In addition, commenters indicated that the 90-day time period reduced administrative burden and allowed for needed time to adapt their EHRs to ensure they could achieve program objectives. As a result, we did not finalize our proposal and established a 90-day EHR reporting period for all EPs in 2015 and for new participants in 2016, as well as a 90-day EHR reporting period for new participants in 2015, 2016, and 2017 with regard to the payment adjustments (80 FR 62777–62779; 62904–62906).

Moving forward, the implementation of MIPS creates a critical opportunity to align performance periods to ensure that quality, CPIA, resource use, and the advancing care information performance categories are all measured and scored based on the same period of time. We believe this would lower reporting burden, focus clinician quality improvement efforts and align administrative actions so that clinicians can use common systems and reporting pathways.

Under MIPS, we propose to align the performance period for the advancing care information performance category to the proposed MIPS performance period of one full calendar year. Thus, the performance period for the advancing care information performance category would be the same as the performance periods for the other performance categories as indicated in section II.E.4. We note that there would not be a separate 90-day performance period for the advancing care information performance category. Under this proposal, MIPS eligible clinicians would need to submit data based on performance period starting January 1, 2017, and ending December 31, 2017 for the first year of MIPS. We recognize that stakeholders may still have concerns related to a full year performance period. We note that, as discussed in section II.E.4. of this proposed rule, MIPS eligible clinicians that only have data for a portion of the year can still submit data, be assessed and be scored for the advancing care information performance category. Under the proposal, MIPS eligible clinicians would need to possess certified EHR technology and report on the objectives and measures (without meeting any thresholds) during the calendar year performance period to achieve the advancing care information category base score. We note that MIPS eligible clinicians would be required to submit all of the data they have available for the performance period, even if the time period they have data for is less than one full calendar year.

We believe this proposal would reduce reporting burden and streamline requirements so that MIPS eligible clinicians and third party intermediaries, such as registries and QCDRs, would have a common timeline for data submission to all performance categories. We refer readers to section II.E.4. of this proposed rule for discussion of the performance period for MIPS and solicit feedback on our proposal.

(5) Advancing Care Information Performance Category Data Submission and Collection

(a) Definition of Meaningful EHR User and Certification Requirements

The use of certified health IT continues to be an important component of care delivery for clinicians. Certified health IT that advances patient engagement, interoperability, and privacy and security are key to care coordination, and a critical component in improving health outcomes.

We anticipate that as certified health IT and related standards continue to evolve to support health information exchange, care coordination (for example, referral management), and other capabilities, we will consider updates to the certified health IT requirements for MIPS. We continue to work with the Office of the National Coordinator for Health IT to identify certified health IT that would aid clinicians in MIPS.

Throughout this proposed rule, we use the terms "certified health IT" and "certified EHR technology". These terms refer to health information technologies and systems that are certified to various standards and functions under the ONC Health IT Certification Program. In general, the full range of potential technologies, functions, standards, and systems for which ONC has established certification criteria are referred to as "certified health IT" (See the 2015 Edition Health IT Certification Criteria final rule (80 FR 62604)). In contrast, the term "certified EHR technology" is a statutory and regulatory term that defines the technology that MIPS eligible clinicians and participants in Advanced APMs must use.

It is important to note that certified EHR technology is a part of the larger category of certified health IT. Therefore when discussing certified health IT in a broad and general manner; such a discussion includes both the functions included in certified EHR technology and other additional potential functions and criteria. In other words, certified EHR technology is a subset of the broader definition of certified health IT.

"Certified health IT" is used in two different ways within this proposed rule. The first is stated as "certified health IT" to identify where the text is referencing a broad range of technology that is included in the ONC Health IT Certification Program. The second use is where the term "a certified Health IT Module" identifies a technology or function used independently from the clinicians' EHR. An example of this second use of the term includes the certified functions leveraged by Health Information Exchange organizations, QCDRs, and public health agencies to support actions like information exchange, quality measurement, and data submission. These individual functions may also be a part of the certified EHR technology definition and may connect with the EHR, but are in these cases used independently from the clinicians' EHR systems.

ONC and CMS worked closely to identify the set of certified health IT that are part of the certified EHR technology definitions proposed in this rule. For example, ONC's 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (80 FR 62602 through 62759) hereinafter referred to as "2015 Edition final rule", defines the technological requirements for health IT systems used by EHR Incentive Program participants. In this proposed rule, we are proposing to adopt a definition of certified EHR technology at § 414.1305 for MIPS eligible clinicians that is based on the definition that applies in the EHR Incentive Programs under 42 CFR 495.4.

In the 2015 EHR Incentive Programs final rule (80 FR 62873) we outlined the requirements for EPs using certified EHR technology in 2017 as it relates to the objectives and measures they select to report. We propose at § 414.1375 similar requirements for the use of certified EHR technology in relation to the selection of objectives and measures under the MIPS advancing care information performance category.

For 2017, the first MIPS performance period, MIPS eligible clinicians would be able to use EHR technology certified to either the 2014 or 2015 Edition certification criteria as follows:

- A MIPS eligible clinician who only has technology certified to the 2015 Edition may choose to report: (1) On the objectives and measures specified for the advancing care information performance category in section II.E.5.g.7 of this proposed rule, which correlate to Stage 3 requirements; or (2) on the alternate objectives and measures specified for the advancing care information performance category in section II.E.5.g.7 of this proposed rule, which correlate to modified Stage 2 requirements.
- A MIPS eligible clinician who has technology certified to a combination of 2015 Edition and 2014 Edition may choose to report: (1) On the objectives and measures specified for the advancing care information performance category in section II.E.5.g.7 of this proposed rule, which correlate to Stage 3; or (2) on the alternate objectives and measures specified for the advancing care information performance category as described in section II.E.5.g.7 of this proposed rule, which correlate to modified Stage 2, if they have the appropriate mix of technologies to support each measure selected.
- A MIPS eligible clinician who only has technology certified to the 2014 Edition would not be able to report on any of the measures specified for the advancing care information performance category described in section II.E.5.g.7 of this proposed rule that correlate to a Stage 3 measure that requires the support of technology certified to the 2015 Edition. These MIPS eligible clinicians would be required to report on the alternate objectives and measures specified for the advancing care information performance category as described in section II.E.5.g.7. of this proposed rule, which correlate to modified Stage 2 objectives and measures.

Beginning with the performance period in 2018, MIPS eligible clinicians:

- Must only use technology certified to the 2015 Edition to meet the objectives and measures specified for the advancing care information performance category in section II.E.5.g.7. of this proposed rule, which correlate to Stage 3.

We welcome comments on this proposal, which is intended to maintain consistency across MIPS, the Medicare EHR Incentive Program and the Medicaid EHR Incentive Program.

Finally, we propose to define at § 414.1305 a meaningful EHR user under MIPS as a MIPS eligible clinician who possesses certified EHR technology, uses the functionality of certified EHR technology, and reports on applicable objectives and measures specified for the advancing care information performance category for a performance period in the form and manner specified by CMS.

We invite comments on our proposals.

(b) Method of Data Submission

Under the Medicare EHR Incentive Program, EPs attest to the numerators and denominators for certain objectives and measures, through a CMS web portal. For the purpose of reporting advancing care information performance category objectives and measures under the MIPS, we propose at § 414.1325 to allow for MIPS eligible clinicians to submit advancing care information performance category data through qualified registry, EHR, QCDR, attestation and CMS Web Interface submission methods. Regardless of data submission method, all MIPS eligible clinicians must follow the reporting requirements for the objectives and measures to meet the requirements of the advancing care information performance category.

We note that under this proposal, 2017 would be the first year that EHRs (through the QRDA submission method), QCDRs and qualified registries would be able to submit EHR Incentive Program objectives and measures (as adopted for the advancing care information performance category) to CMS, and the first time this data would be reported through the CMS Web Interface. We recognize that some Health IT vendors, QCDRs and qualified registries may not be able to conduct this type of data submission for the 2017 performance period given that the development efforts associated with this data submission capability. However, we are including these data submission mechanisms in 2017 to support early adopters and to signal our longer-term commitment to working with organizations that are agile, effective and can create less burdensome data submission mechanisms for MIPS eligible clinicians. We believe the proposed data submission methods could reduce reporting burden by synchronizing reporting requirements and data submission, and systems, allow for greater access and ease in submitting data throughout the MIPS program. We note that specific details about the form and manner for data submission will be addressed by CMS in the future.

(c) Group Reporting

Under the Medicare EHR Incentive Program, CMS adopted a reporting mechanism for EPs that are part of a group to attest using one common form, or batch reporting process. Under that batch reporting process CMS assessed the individual performance of the EPs that made up the group, not the group as a whole, to determine whether those EPs meaningfully used certified EHR technology.

The structure of the MIPS and our desire to achieve alignment across the MIPS performance categories appropriately necessitates the ability to assess the performance of MIPS eligible clinicians at the group level for all MIPS performance categories. We believe MIPS eligible clinicians should be able to submit data as a group, and be assessed at the group level, for all of the MIPS performance categories, including the advancing care information performance category. For this reason, we are proposing a group reporting mechanism for individual MIPS eligible clinicians to have their performance assessed as a group for all performance categories in section II.E.1.e. of this proposed rule, consistent with section 1848(q)(1)(D)(i)(I) & (II) of the Act.

Under this option, we are proposing that performance on advancing care information performance category objectives and measures would be assessed and reported at the group level, as opposed to the individual MIPS eligible clinician level. We note that the data submission criteria would be the same when submitted at the group-level as if submitted at the individual-level, but the data submitted would be aggregated for all MIPS eligible clinicians within the group practice. We believe this approach to data submission better reflects the team dynamics of groups, and would reduce the overall reporting burden for MIPS eligible clinicians that practice in groups, incentivize practice-wide approaches to data submission, and provide enterprise-level continuous improvements strategies for submitting data to the advancing care information performance category. Please see section II.E.1.e. of this proposed rule for more discussion of how to participate as a group under MIPS.

(6) Reporting Requirements & Scoring Methodology

(a) Scoring Method

Section 1848(q)(5)(E)(i)(IV) of the Act, as added by section 101(c) of the MACRA, states that 25 percent of the MIPS CPS shall be based on performance for the advancing care information performance category. Therefore, we propose at § 414.1375 that performance in the advancing care information performance category will comprise 25 percent of a MIPS eligible clinician's CPS for payment year 2019 and each year thereafter. We received many comments in the MIPS and APMs RFI from stakeholders regarding the importance of flexible scoring for the advancing care information performance category and provisions for multiple performance pathways. We agree that this is the best approach moving forward with the adoption and use of certified EHR technology as it becomes part of a single coordinated program under the MIPS. For the reasons described here and previously in this preamble, we are proposing a methodology which balances the goals of incentivizing participation and reporting while recognizing exceptional performance by awarding points through a performance score. In this methodology, we are proposing at § 414.1380(b)(4) that the score for the advancing care information performance category would be comprised of a score for participation and reporting, hereinafter referred to as the "base score," and a score for performance at varying levels above the base score requirements, hereinafter referred to as the "performance score".

(b) Base Score

To earn points toward the base score, a MIPS eligible clinician must report the numerator and denominator of certain measures specified for the advancing care information performance category (see measure specifications in section II.E.5.g.7 of this proposed rule), which are based on the measures adopted by the EHR Incentive Programs for Stage 3 in the 2015 EHR Incentive Programs Final Rule, to account for 50 percent (out of a total 100 percent) of the advancing care information performance category score. For measures that include a percentage-based threshold for Stage 3 of the EHR Incentive Program, we would not require those thresholds to be met for purposes of the advancing care information performance category under MIPS, but would instead require MIPS eligible clinicians to report the numerator (of at least one) and denominator (or a yes/no statement for applicable measures, which would be submitted together with data for the other measures) for each measure being reported. We note that for any measure requiring a yes/no statement, only a yes statement would qualify for credit under the base score. Under the proposal, the base score of the advancing care information performance category would incorporate the objective and measures adopted by the EHR Incentive Programs with an emphasis on privacy and security. We are proposing two variations of a scoring methodology for the base score, a primary and an alternate proposal, which are outlined below. Both proposals would require the MIPS eligible clinician to meet the requirement to protect patient health information created or maintained by certified EHR technology to earn any score within the advancing care information performance category; failure to do so would result in a base score of zero, a performance score of zero (discussed in section II.E.5.g of this proposed rule), and an advancing care information performance category score of zero.

The primary proposal at section II.E.5.g.6.b.ii. of this proposed rule would require a MIPS eligible clinician to report the numerator (of at least one) and denominator or yes/no statement (only a yes statement would qualify for credit under the base score) for a subset of measures adopted by the EHR Incentive Program for EPs in the 2015 EHR Incentive Programs Final Rule. In an effort to streamline and simplify the reporting requirements under the MIPS, and reduce reporting burden on MIPS eligible clinicians, two objectives (Clinical Decision Support and Computerized Provider Order Entry) and their associated measures would not be required for reporting the advancing care information performance category. Given the consistently high performance on these two objectives in the EHR Incentive Program with EPs accomplishing a median score of over 90 percent for the last 3 years, we believe these objectives and measures are no longer an effective measure of EHR performance and use. In addition, we do not believe these objectives and associated measures contribute to the goals of patient engagement and interoperability, and thus believe these objectives can be removed in an effort to reduce reporting burden without negatively impacting the goals of the advancing care information performance category. We note that the removed objectives and associated measures would still be required as part of ONC's functionality standards for certified EHR technology, however, MIPS eligible clinicians would not be required to report the numerator and denominator or yes/no statement for those measures. In the 2015 EHR Incentive Programs Final Rule we also established that, for measures that were removed, the technology requirements would still be a part of the definition of certified EHR technology. For example, in that final rule, the Stage 1 Objective to Record Demographics was removed, but the technology and standard for this function in the EHR were still required (80 FR 62784). This means that the MIPS eligible clinician would still be required to have these functions as a part of their certified EHR technology.

The alternate proposal at section II.E.5.g.6.b.iii. of this proposed rule would require a MIPS eligible clinician to report the numerator (of at least one) and denominator or yes/no statement (only a yes statement would qualify for credit under the base score) for all objectives and measures adopted for Stage 3 in the 2015 EHR Incentive Programs Final Rule to earn the base score portion of the advancing care information performance category, which would include reporting a yes/no statement for Clinical Decision Support and a numerator and denominator for Computerized Provider Order Entry objectives. We include these objectives in the alternate proposal as MIPS eligible clinicians may feel the continued measurement of these objectives is valuable to the continued use of EHR technology as this would maintain the previously established objectives under the EHR Incentive Program.

We believe both proposed approaches to the base score are consistent with the statutory requirements and previously established certified EHR technology requirements as we transition to MIPS. We also believe both approaches, in conjunction with the advancing care information performance score, recognize the need for greater flexibility in scoring CEHRT use across different clinician types and practice settings by allowing MIPS eligible clinicians to focus on the objectives and measures most applicable to their practice.

(i) Privacy and Security; Protect Patient Health Information

In the 2015 EHR Incentive Programs Final Rule (80 FR 62832), we finalized the Protect Patient Health Information objective and its associated measure for Stage 3, which requires EPs to protect electronic protected health information (ePHI) created or maintained by the certified EHR technology through the implementation of appropriate technical, administrative, and physical safeguards. As privacy and security is of paramount importance and applicable across all objectives, the Protect Patient Health Information objective and measure would be an overarching requirement for the base score under both the primary proposal and alternate proposal, and therefore would be an overarching requirement for the advancing care information performance category. We propose that a MIPS eligible clinician must meet this objective and measure in order to earn any score within the advancing care information performance category. Failure to do so would result in a base score of zero under either the primary proposal or alternate proposal outlined below, as well as a performance score of zero (discussed in section II.E.5.g. of this proposed rule) and an advancing care information performance category score of zero.

(ii) Advancing Care Information Performance Category Base Score Primary Proposal

In the 2015 EHR Incentive Programs Final Rule (80 FR 62829–62871), we finalized certain objectives and measures EPs would report to demonstrate meaningful use of certified EHR technology for Stage 3. Under our proposal for the base score of the advancing care information performance category, MIPS eligible clinicians would be required to submit the numerator (of at least one) and denominator, or yes/no statement as appropriate (only a yes statement would qualify for credit under the base score), for each measure within a subset of objectives (Electronic Prescribing, Patient Electronic Access to Health Information, Care of Coordination Through Patient Engagement, Health Information Exchange, and Public Health and Clinical Data Registry Reporting) adopted in the 2015 EHR Incentive Programs Final Rule for Stage 3 as outlined in Table 6 to account for the base score of 50 percent of the advancing care information performance category score. Successfully submitting a numerator and denominator or yes/no statement for each measure of each objective would earn a base score of 50 percent for the advancing care information performance category. Failure to meet the submission criteria (numerator/denominator or yes/no statement as applicable) and measure specifications (as defined in section II.E.5.g.7. of this proposed rule) for any measure in any of the objectives would result in a score of zero for the advancing care information performance category base score, a performance score of zero (discussed in section II.E.5.g. of this proposed rule) and an advancing care information performance category score of zero.

For the Public Health and Clinical Data Registry Reporting objective there is no numerator and denominator to measure; rather, the measure is a "yes/no" statement of whether the MIPS eligible clinician has completed the measure, noting that only a yes statement would qualify for credit under the base score. Therefore we are proposing that MIPS eligible clinicians would include a yes/no statement in lieu of the numerator/denominator statement within their submission for the advancing care information performance category for the Public Health and Clinical Data Registry Reporting objective. We further propose that, to earn points in the base score, a MIPS eligible clinician would only need to complete submission on the Immunization Registry Reporting measure of this objective. Completing any additional measures under this objective would earn one additional bonus point in the advancing care information performance category score. For further information on this proposed objective, we direct readers to section II.E.5.g.7. of this proposed rule.

TABLE 6: Base Score Primary Proposal Advancing Care Information Objective and Measure Reporting*

	Objective	Measure*	Total Base Score
1	Protect Patient Health Information	Security Risk Analysis	50 %
2	Electronic Prescribing	ePrescribing	
3	Patient Electronic Access	Patient Access	
		Patient-Specific Education	
4	Coordination of Care Through Patient Engagement	View, Download or Transmit (VDT)	
		Secure Messaging	
		Patient-Generated Health Data	
5	Health Information Exchange	Patient Care Record Exchange	
		Request/Accept Patient Care Record	
		Clinical Information Reconciliation	
6	Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	
		(Optional) Syndromic Surveillance Reporting	
		(Optional) Electronic Case Reporting	
		(Optional) Public Health Registry Reporting	
		(Optional) Clinical Data Registry Reporting	

*More detailed specifications can be found in Section II.E.5.g.7.

(iii) Advancing Care Information Performance Category Base Score Alternate Proposal

Under our alternate proposal for the base score of the advancing care information performance category, a MIPS eligible clinician would be required to submit the numerator (of at least one) and denominator, or yes/no statement as appropriate, for each measure, for all objectives and measures for Stage 3 in the 2015 EHR Incentives Program Final Rule (80 FR 62829–62871) as outlined in Table 7. Successfully submitting a numerator and denominator for each measure of each objective would earn a base score of 50 percent for the advancing care information performance category. Failure to meet the submission requirements, or measure specifications for any measure in any of the objectives would result in a score of zero for the advancing care information performance category base score, a performance score of zero (discussed in Section II.E.5.g.), and an advancing care information performance category score of zero.

We propose the same approach in the alternate proposal for the Public Health and Clinical Data Registry Reporting objective as for the primary proposal outlined above. We direct readers to section II.E.5.g.7. for further details on the individual objectives and measures.

TABLE 7: Base Score Alternate Proposal Advancing Care Information Objective and Measure Reporting

	Objective	Measure*	Total Base Score
1	Protect Patient Health Information	Security Risk Analysis	50 %
2	Electronic Prescribing	ePrescribing	
3	Clinical Decision Support (CDS)	Clinical Decision Support (CDS) Interventions	
		Drug Interaction and Drug-Allergy Checks	
4	Computerized Provider Order Entry (CPOE)	Medication Orders	
		Laboratory Orders	
		Diagnostic Imaging Orders	
5	Patient Electronic Access	Patient Access	
		Patient-Specific Education	
6	Coordination of Care Through Patient Engagement	View, Download or Transmit (VDT)	
		Secure Messaging	
		Patient-Generated Health Data	
7	Health Information Exchange	Patient Care Record Exchange	
		Request/Accept Patient Care Record	
		Clinical Information Reconciliation	
8	Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	
		(Optional) Syndromic Surveillance Reporting	
		(Optional) Electronic Case Reporting	
		(Optional) Public Health Registry Reporting	
		(Optional) Clinical Data Registry Reporting	

*More detailed specifications can be found in section II.E.5.g.7.

(iv) Modified Stage 2 in 2017

In the 2015 EHR Incentive Programs final rule (80 FR 62772), we streamlined reporting for EPs by adopting a single set of objectives and measures for EPs regardless of their prior stage of participation. This was the first step in synchronizing the objectives and eliminating the separate stages of meaningful use in the EHR Incentive Program. In doing so, we also sought to provide some flexibility and to allow adequate time for EPs to move toward the more advanced use of EHR technology. This flexibility included alternate exclusions and specifications for EPs scheduled to demonstrate Stage 1 in 2015 and 2016 (80 FR 62788) and allowed clinicians to select either the Modified Stage 2 Objectives or the Stage 3 Objectives in 2017 (80 FR 62772) with all EPs moving to the Stage 3 Objectives in 2018. We note that in section II.E.5.g. of this proposed rule, we proposed the requirements for MIPS eligible clinicians using various editions of certified EHR technology in 2017 as it relates to the objectives and measures they select to report.

In connection with that proposal, and in an effort not to unfairly burden MIPS eligible clinicians who are still utilizing EHR technology certified to the 2014 Edition certification criteria in 2017, we propose at § 414.1380(b)(4) modified primary and alternate proposals for the base score for those MIPS eligible clinicians utilizing EHR technology certified to the 2014 Edition. We note that these modified proposals are the same as the primary and alternate proposals outlined above in regard to scoring and data submission, but vary in the measures required under the Coordination of Care Through Patient Engagement and Health Information Exchange objectives as demonstrated in Table 8.

This approach allows MIPS eligible clinicians to continue moving toward advanced use of certified EHR technology in 2018, but allows for flexibility in the implementation of upgraded technology and in the selection of measures for reporting in 2017.

We invite comments on our proposal.

TABLE 8: Base Score Modified Primary and Alternate Proposals Advancing Care Information Objective and Measure Reporting for Modified Stage 2 (in 2017)

Objective	Measure for MIPS (in 2017 only)**	Total Base Score
Protect Patient Health Information	Security Risk Analysis	50%
Electronic Prescribing	ePrescribing	
Clinical Decision Support (CDS)*	Clinical Decision Support (CDS) Interventions	
	Drug Interaction and Drug-Allergy Checks	
Computerized Provider Order Entry (CPOE)*	Medication Orders	
	Laboratory Orders	
	Diagnostic Imaging Orders	
Patient Electronic Access	Patient Access	
	View, Download, or Transmit (VDT)	
Patient-Specific Education	Patient-Specific Education	
Secure Messaging	Secure Messaging	
Health Information Exchange	Health Information Exchange	
Medication Reconciliation	Medication Reconciliation	
Public Health Reporting	Immunization Registry Reporting	
	Syndromic Surveillance Reporting	
	Specialized Registry Reporting	

*Included in base score alternate proposal only.

**More detailed specifications can be found in section II.E.5.g.7.

(c) Performance Score

In addition to the base score, which includes submitting each of the objectives and measures in order to achieve 50 percent of the possible points within the advancing care information performance category, we propose to allow multiple paths to achieve a score greater than the 50 percentage base score. The performance score is based on the priority goals established by CMS to focus on leveraging certified EHR technology to support the coordination of care. A MIPS eligible clinician would earn additional points above the base score for performance in the objectives and measures for Patient Electronic Access, Coordination of Care through Patient Engagement, and Health Information Exchange. These measures have a focus on patient engagement, electronic access and information exchange, which promote healthy behaviors by patients and lay the ground work for interoperability. These measures also have significant opportunity for improvement among eligible clinicians and the industry as a whole based on adoption and performance data. We believe this approach for achievement above a base score in the advancing care information performance category would provide MIPS eligible clinicians a flexible and realistic incentive towards the adoption and use of certified EHR technology.

We are proposing at § 414.1380(b)(4) that, for the performance score, the eight associated measures under these three objectives would each be assigned a total of 10 possible points. For each measure, a MIPS eligible clinician may earn up to 10 percent of their performance score based on their performance rate for the given measure. For example, a performance rate of 95 percent on a given measure would earn 9.5 percentage points of the performance score for the advancing care information performance category. This scoring approach is consistent with the performance score approach outlined for other MIPS categories in this proposed rule. Table 9 provides an example of the proposed performance score methodology.

TABLE 9: Sample Performance Score

Objectives	**Patient Electronic Access**		**Coordination of Care Through Patient Engagement**			**Health Information Exchange (HIE)**		
Measures	Patient Access	Patient-Specific Education	VDT	Secure Messaging	Patient-Generated health Data	Patient Care Record Exchange	Request/ Accept Patient Care Record	Clinical Information Reconciliation
Performance Rate Score								
	95%							
		65%						
								57%
			33%	31%			38%	
					25%	21%		
Percentage Points Earned	9.5%	6.5%	3.3%	3.1%	2.5%	2.1%	3.8%	5.7%
Performance Score = 36.5 percent								

We note that in this methodology, a MIPS eligible clinician has the potential to earn a performance score of up to 80 percent, which, in combination with the base score would be greater than the total possible 100 percent for the advancing care information performance category. This methodology allows flexibility for MIPS eligible clinicians to focus on measures which are most relevant to their practice to achieve the maximum performance category score, while deemphasizing concentration in other measures which are not relevant to their practice.

This proposed methodology recognizes the importance of promoting health IT adoption and standards and the use of certified EHR technology to support quality improvement, interoperability, and patient engagement. We invite comments on our proposal.

(d) Overall Advancing Care Information Performance Category Score

To determine the MIPS eligible clinician's overall advancing care information performance category score, we propose to use the sum of the base score, performance score, and the potential Public Health and Clinical Data Registry Reporting bonus point. We note that if the sum of the MIPS eligible profession's base score (50 percent) and performance score (out of a possible 80 percent) with the Public Health and Clinical Data Registry Reporting bonus point are greater than 100 percent, we would apply an advancing care information performance category score of 100 percent. For example, if the MIPS eligible clinician earned the base score of 50 percent, a performance score of 60 percent and the bonus point for Public Health and Clinical Data Registry Reporting for a total of 111 percent, the MIPS eligible clinician's overall advancing care information performance category score would be 100 percent. The total percentage score (out of 100) for the advancing care information performance category would then be applied to the 25 points allocated for the advancing care information performance category and incorporated into the MIPS CPS, as described in section II.E.6. of this proposed rule. Table 10 provides an example of the calculation of the advancing care information performance category score based on these proposals.

TABLE 10: Sample Advancing Care Information Performance Category Score

Base Score		Performance Score Components								Total Performance Score	Public Health and Clinical Data Registry Bonus Point	Total Percentage
Protect Patient Health Information	Objectives and Measures	Patient Electronic Access		Coordination of Care Through Patient Engagement			Health Information Exchange					
50%		9.5%	6.5%	3.3%	3.1%	2.5%	2.1%	3.8%	5.7%	36.5 %	1%	87.5%
87.5% of 25 possible percentage points = 21.88 percentage points for the advancing care information performance category												

(e) Scoring Considerations

Section 1848(q)(5)(E)(ii) of the Act, as added by section 101(c) of the MACRA, provides that in any year in which the Secretary estimates that the proportion of EPs (as defined in section 1848(o)(5) of the Act) who are meaningful EHR users (as determined under section 1848(o)(2) of the Act) is 75 percent or greater, the Secretary may reduce the applicable percentage weight of the advancing care information performance category in the MIPS CPS, but not below 15 percent, and increase the weightings of the other performance categories such that the total percentage points of the increase equals the total percentage points of the reduction. We note section 1848(o)(5) of the Act defines an EP as a physician, as defined in section 1861(r) of the Act. For purposes of applying section 1848(q)(5)(E)(ii) of the Act, we propose to estimate the proportion of physicians as defined in section 1861(r) who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of at least 75 percent under our proposed scoring methodology for the advancing care information performance category for a performance period. This would require the MIPS eligible clinician to earn the advancing care information base score of 50 percent, and an advancing care information performance score of at least 25 percent (or 24 percent plus the Public Health and Clinical Data Registry Reporting bonus point) for an overall performance category score of 75 percent for the advancing care information performance category. We are alternatively proposing to estimate the proportion of physicians as defined in section 1861(r) who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of 50 percent (which would only require the MIPS eligible clinician to earn the advancing care information base score) under our proposed scoring methodology for the advancing care information performance category for a performance period, and we seek comments on both of these proposed thresholds.

We propose to base this estimation on data from the relevant performance period, if we have sufficient data available from that period. For example, if feasible, we would consider whether to reduce the applicable percentage weight of the advancing care information performance category in the MIPS CPS for the 2019 MIPS payment year based on an estimation using the data from the 2017 performance period. We note that in section II.E.5.g.8. of this proposed rule, we have proposed to reweight the advancing care information performance category to zero for certain hospital-based physicians and other physicians. These physicians meet the definition of MIPS eligible clinicians, but would not be included in the estimation because the advancing care information performance category would be weighted at zero for them. We note that any adjustments of the performance category weights specified in section 1848(q)(5)(E) of the Act based on this policy would be established in future notice and comment rulemaking.

We invite comments on our proposals.

(7) Advancing Care Information Performance Category Objectives and Measures Specifications

(a) MIPS Objectives and Measures Specifications

We propose the objectives and measures for the advancing care information performance category of MIPS as outlined in this section of the proposed rule. We note that these objectives and measures have been adapted from the Stage 3 objectives and measures as finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62829–62871), however, we have not proposed to maintain the previously established thresholds for MIPS. Any additional changes to the objectives and measures are outlined in this section of the proposed rule. For a more detailed discussion of the Stage 3 objectives and measures, including explanatory material and defined terms, we refer readers to the 2015 EHR Incentive Programs Final Rule (80 FR 62829–62871).

Objective: Protect Patient Health Information

Objective: Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology through the implementation of appropriate technical, administrative, and physical safeguards

Security Risk Analysis Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified EHR technology in accordance with requirements in 45 CFR164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.

Objective: Electronic Prescribing

Objective: MIPS eligible clinicians must generate and transmit permissible prescriptions electronically.

ePrescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using certified EHR technology.

- Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.
- Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using certified EHR technology.

For this objective, we note that the 2015 EHR Incentive Program final rule included a discussion of controlled substances in the context of the Stage 3 objective and measure (80 FR 62834), which we understand from stakeholders has caused confusion. We are therefore proposing for both MIPS and for the EHR Incentive Programs that health care providers would continue to have the option to include or not include controlled substances that can be electronically prescribed in the denominator. This means that health care providers may choose to include controlled substances in the definition of "permissible prescriptions" at their discretion where feasible and allowable by law in the jurisdiction where they provide care. The health care provider may also choose not to include controlled substances in the definition of "permissible prescriptions" even if such electronic prescriptions are feasible and allowable by law in the jurisdiction where they provide care.

Objective: Clinical Decision Support (Alternate Proposal Only)

Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions

Clinical Decision Support (CDS) Interventions Measure: Implement three clinical decision support interventions related to three CQMs at a relevant point in patient care for the entire performance period. Absent three CQMs related to a MIPS eligible clinician's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Drug Interaction and Drug-Allergy Checks Measure: The MIPS eligible clinician has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire performance period.

Objective: Computerized Provider Order Entry (Alternate Proposal Only)

Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

Medication Orders Measure: At least one medication order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of medication orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Laboratory Orders Measure: At least one laboratory order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of laboratory orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Diagnostic Imaging Orders Measure: At least one diagnostic imaging order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of diagnostic imaging orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Objective: Patient Electronic Access.

Objective: The MIPS eligible clinician provides patients (or patient authorized representative) with timely electronic access to their health information and patient-specific education.

Patient Access Measure: For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient—authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's certified EHR technology.

- Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's certified EHR technology.

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician.

- Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from certified EHR technology during the performance period.

Objective: Coordination of Care Through Patient Engagement.

Objective: Use certified EHR technology to engage with patients or their authorized representatives about the patient's care.

View, Download, Transmit (VDT) Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician. An MIPS eligible clinician may meet the measure by either—(1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's certified EHR technology; or (3) a combination of (1) and (2).

- Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the performance period.

Secure Messaging Measure: For at least one unique patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of certified EHR technology to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

- Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the performance period.

Patient-Generated Health Data Measure: Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for at least one unique patient seen by the MIPS eligible clinician during the performance period.

- Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the certified EHR technology into the patient record during the performance period.

Objective: Health Information Exchange.

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of certified EHR technology.

Patient Care Record Exchange Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider—(1) creates a summary of care record using certified EHR technology; and (2) electronically exchanges the summary of care record.

- Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.
- Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

Request/Accept Patient Care Record Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.

- Denominator: Number of patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.
- Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the clinician into the certified EHR technology.

Clinical Information Reconciliation Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician performs clinical information reconciliation. The clinician must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication. (2) Medication allergy. Review of the patient's known medication allergies. (3) Current Problem list. Review of the patient's current and active diagnoses.

- Denominator: Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.
- Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list, medication allergy list, and current problem list.

Objective: Public Health and Clinical Data Registry Reporting

Objective: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(Optional) Syndromic Surveillance Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting where the jurisdiction accepts syndromic data from such settings and the standards are clearly defined.

(Optional) Electronic Case Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.

(Optional) Public Health Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.

(Optional) Clinical Data Registry Reporting Measure: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.

(b) Modified Stage 2 Advancing Care Information Objectives and Measures Specifications for MIPS

We propose the Modified Stage 2 objectives and measures for the advancing care information performance category of MIPS as outlined in this section of the proposed rule. We note that these objectives and measures have been adapted from the Modified Stage 2 objectives and measures as finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62793—62825), however, we have not proposed to maintain the previously established thresholds for MIPS. Any additional changes to the objectives and measures are outlined in this section of the proposed rule. For a more detailed discussion of the Modified Stage 2 objectives and measures, including explanatory material and defined terms, we refer readers to the 2015 EHR Incentive Programs Final Rule (80 FR 62793—62825).

Objective: Protect Patient Health Information

Objective: Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology through the implementation of appropriate technical, administrative, and physical safeguards.

Security Risk Analysis Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified EHR technology in accordance with requirements in 45 CFR164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.

Objective: Electronic Prescribing

Objective: MIPS eligible clinicians must generate and transmit permissible prescriptions electronically.

ePrescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using certified EHR technology.

- Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.
- Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using certified EHR technology.

Objective: Clinical Decision Support (alternate proposal only)

Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

Clinical Decision Support (CDS) Interventions Measure: Implement three clinical decision support interventions related to three CQMs at a relevant point in patient care for the entire performance period. Absent three CQMs related to a MIPS eligible clinician's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Drug Interaction and Drug-Allergy Checks Measure: The MIPS eligible clinician has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire performance period.

Objective: Computerized Provider Order Entry

Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

Medication Orders Measure: At least one medication order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of medication orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Laboratory Orders Measure: At least one laboratory order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of laboratory orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Diagnostic Imaging Orders Measure: At least one diagnostic imaging order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of diagnostic imaging orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Objective: Patient Electronic Access

Objective: The MIPS eligible clinician provides patients (or patient authorized representative) with timely electronic access to their health information and patient-specific education.

Patient Access Measure: At least one patient seen by the MIPS eligible clinician during the performance period is provided timely access to view online, download, and transmit to a third party their health information subject to the MIPS eligible clinician's discretion to withhold certain information.

- Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party.

View, Download, Transmit (VDT) Measure: At least one patient seen by the MIPS eligible clinician during the performance period (or patient-authorized representative) views, downloads or transmits their health information to a third party during the performance period.

- Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period.

Objective: Patient-Specific Education

Objective: The MIPS eligible clinician provides patients (or patient authorized representative) with timely electronic access to their health information and patient-specific education.

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide access to those materials to at least one unique patient seen by the MIPS eligible clinician.

- Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator who were provided access to patient-specific educational resources using clinically relevant information identified from certified EHR technology during the performance period.

Objective: Secure Messaging

Objective: Use certified EHR technology to engage with patients or their authorized representatives about the patient's care.

Secure Messaging Measure: For at least one patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of certified EHR technology to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient authorized representative) during the performance period.

- Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the performance period.

Objective: Health Information Exchange

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of certified EHR technology.

Health Information Exchange Measure: The MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) uses certified EHR technology to create a summary of care record; and (2) electronically transmits such summary to a receiving health care provider for at least one transition of care or referral.

- Denominator: Number of transitions of care and referrals during the performance period for which the EP was the transferring or referring health care provider.
- Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

Objective: Medication Reconciliation

Medication Reconciliation Measure: The MIPS eligible clinician performs medication reconciliation for at least one transition of care in which the patient is transitioned into the care of the MIPS eligible clinician.

- Denominator: Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.
- Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list, medication allergy list, and current problem list.

Objective: Public Health Reporting

Objective: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data.

Syndromic Surveillance Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data.

Specialized Registry Reporting Measure: The MIPS eligible clinician is in active engagement to submit data to a specialized registry.

We invite comments on our proposal.

(c) Exclusions

In the 2015 EHR Incentive Programs Final Rule (80 FR 62829–62871) we outlined certain exclusions from the objectives and measures of meaningful use for EPs who perform low numbers of a particular action or activity for a given measure (for example, an EP who writes fewer than 100 permissible prescriptions during the EHR reporting period would be granted an exclusion for the Electronic Prescribing measure) or for EPs who had no office visits during the EHR reporting period. Moving forward, we believe that the proposed MIPS exclusion criteria as outlined in section II.E.3. of this proposed rule, and advancing care information performance category scoring methodology together accomplish the same end as the previously established exclusions for the majority of the advancing care information measures. By excluding from MIPS those clinicians who do not exceed the low-volume threshold (proposed in section II.E.3.c. as MIPS eligible clinicians who, during the performance period, have Medicare billing charges less than or equal to $10,000 and provide care for 100 or fewer Part B-enrolled Medicare beneficiaries), we believe exclusions for most of the individual advancing care information measures are no longer necessary. The additional flexibility afforded by the proposed advancing care information performance category scoring methodology eliminates required thresholds for measures and allows MIPS eligible clinicians to focus on, and therefore report higher numbers for, measures that are more relevant to their practice.

We note that EPs who write less than 100 permissible prescriptions during the EHR reporting period are allowed an exclusion for the Electronic Prescribing measure under the EHR Incentive Program (80 FR 62834), which we do not propose for MIPS. We note that the Electronic Prescribing objective would not be part of the performance score under our proposals, and thus MIPS eligible clinicians who write very low numbers of permissible prescriptions would not be at a disadvantage in relation to other MIPS eligible clinicians when seeking to achieve a maximum advancing care information performance category score. For the purposes of the base score, we are proposing that those MIPS eligible clinicians who write fewer than 100 permissible prescriptions in a performance period may elect to report their numerator and denominator (if they have at least one permissible prescription for the numerator), or they may report a null value. This is consistent with prior policy which allowed flexibility for clinicians in similar circumstances to choose an alternate exclusion (80 FR 62789).

In addition, in the 2015 EHR Incentive Programs final rule, we adopted a set of exclusions for the Immunization Registry Reporting measure under the Public Health and Clinical Data Registry Reporting objective (80 FR 62870). We recognize that some types of clinicians do not administer immunizations, and are therefore proposing to maintain the previously established exclusions for the Immunization Registry Reporting measure. We are therefore proposing that these MIPS eligible clinicians may elect to report their yes/no statement if applicable, or they may report a null value (if the previously established exclusions apply) for purposes of reporting the base score.

We note that we are not proposing to maintain any of the other exclusions established under the EHR Incentive Program, however, we are seeking comment on whether other exclusions should be considered under the advancing care information performance category under the MIPS.

(8) Additional Considerations

(a) Reweighting of the Advancing Care Information Performance Category for MIPS Eligible Clinicians Without Sufficient Measures Applicable and Available

As discussed previously in this proposed rule, section 101(b)(1)(A) of the MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment at the end of CY 2018. Section 1848(a)(7) of the Act includes certain statutory exceptions to the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act. Specifically, section 1848(a)(7)(D) of the Act exempts hospital-based EPs from the application of the payment adjustment under section 1848(a)(7)(A) of the Act. In addition, section 1848(a)(7)(B) of the Act provides that the Secretary may exempt an EP who is not a meaningful EHR user for the EHR reporting period for the year from the application of the payment adjustment under section 1848(a)(7)(A) of the Act if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient internet access. The MACRA did not maintain these statutory exceptions for the advancing care information performance category of the MIPS. Thus, the exceptions under sections 1848(a)(7)(B) and (D) of the Act are limited to the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act and do not apply in the context of the MIPS.

Section 1848(q)(5)(F) of the Act provides, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to each type of MIPS eligible clinician, and for each measure and activity specified for each such category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician.

We believe that under our proposals for the advancing care information performance category of the MIPS, there may not be sufficient measures that are applicable and available to certain types of MIPS eligible clinicians as outlined in this section of this proposed rule, some of whom may have qualified for a statutory exception to the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act. For the reasons stated below, we propose to assign a weight of zero to the advancing care information performance category for purposes of calculating a MIPS CPS for these MIPS eligible clinicians. We refer readers to section II.E.6. of this proposed rule for more information regarding how the quality, resource use and CPIA performance categories would be reweighted.

(i) Hospital-Based MIPS Eligible Clinicians

Section 1848(a)(7)(D) of the Act exempts hospital-based EPs from the application of the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act. We defined a hospital-based EP for the EHR Incentive Program under § 495.4 as an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before the year preceding such payment adjustment year. Under this definition, EPs that have 90 percent or more of payments for covered professional services associated with claims with Place of Service Codes 21 (inpatient hospital) or 23 (emergency department) are considered hospital-based (75 FR 44442).

We believe there may not be sufficient measures applicable and available to hospital-based MIPS eligible clinicians under our proposals for the advancing care information performance category of MIPS.

Hospital-based MIPS eligible clinicians may not have control over the decisions that the hospital makes regarding the use of health IT and certified EHR technology. These MIPS eligible clinicians therefore may have no control over the type of certified EHR technology available, the way that the technology is implemented and used, or whether the hospital continually invests in the technology to ensure it is compliant with ONC certification criteria. In addition, some of the specific advancing care information performance category measures, such as the Patient Access measure under the Patient Electronic Access objective requires that patients have access to view, download and transmit their health information from the EHR which is made available by the health care provider, in this case the hospital. Thus the measure is more attributable and applicable to the hospital and not to the MIPS eligible clinician, as the hospital controls the availability of the EHR technology. Further, the requirement under the Protect Patient Health Information objective to conduct a security risk analysis, would rely on the actions of the hospital, rather than the actions of the MIPS eligible clinician, as the hospital controls the access and availability and secure implementation of the EHR technology. In this case, the measure is again more attributable and applicable to the hospital than to the MIPS eligible clinician. Further, certain specialists (such as pathologists, radiologists and anesthesiologists) who often practice in a hospital setting and may be hospital-based MIPS eligible clinicians often lack face-to-face interaction with patients, and thus may not have sufficient measures applicable and available to them under our proposals. For example, hospital-based MIPS eligible clinicians who lack face-to-face patient interaction may not have patients for which they could transfer or create an electronic summary of care record.

In addition, we note that eligible hospitals and CAHs are subject to meaningful use requirements under sections 1886(b)(3)(B) and (n) and 1814(l) of the Act, respectively, which were not affected by the enactment of the MACRA. Eligible hospitals and CAHs are required to report on objectives and measures of meaningful use under the EHR Incentive Program, as outlined in the 2015 EHR Incentive Programs Final Rule. We note the objectives and measures of the EHR Incentive Programs for eligible hospitals and CAHs are specific to these facilities, and are more applicable and better represent the EHR technology available in these settings.

For these reasons, we propose to rely on section 1848(q)(5)(F) of the Act to assign a weight of zero to the advancing care information performance category for hospital-based MIPS eligible clinicians. We propose to define a "hospital-based MIPS eligible clinician" at § 414.1305 as a MIPS eligible clinician who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the performance period, otherwise stated as the year three years preceding the MIPS payment year. For example, under this proposal, hospital-based determinations would be made for the 2019 MIPS payment year based on covered professional services furnished in 2016. We also propose, consistent with the EHR Incentive Program, that CMS would determine which MIPS eligible clinicians qualify as "hospital-based" for a MIPS payment year. We invite comments on these proposals.

In addition, we are seeking comment on how the advancing care information performance category could be applied to hospital-based MIPS eligible clinicians in future years of MIPS, and the types of measures that would be applicable and available to these types of MIPS eligible clinicians.

We are also seeking comment on whether the previously established 90 percent threshold of payments for covered professional services associated with claims with Place of Service (POS) Codes 21 (inpatient hospital) or 23 (emergency department) is appropriate, or whether we should consider lowering this threshold to account for hospital-based MIPS eligible clinicians who bill more than 10 percent of claims with a POS other than 21 or 23. Although we have proposed a threshold of 90 percent, we are considering whether a lower threshold would be more appropriate for hospital-based MIPS eligible clinicians. In particular, we are interested in what factors should be applied to determine the threshold for hospital-based MIPS eligible clinicians. We will continue to evaluate the data to determine whether there are certain thresholds which naturally define a hospital-based MIPS eligible clinician.

(ii) MIPS Eligible Clinicians Facing a Significant Hardship

Section 1848(a)(7)(B) of the Act provides that the Secretary may exempt an EP who is not a meaningful EHR user for the EHR reporting period for the year from the application of the payment adjustment under section 1848(a)(7)(A) of the Act if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship. In the Stage 2 Final Rule (77 FR 54097–54100), we defined certain categories of significant hardships that may prevent an EP from meeting the requirements of being a meaningful EHR user. These categories include:

- Insufficient Internet Connectivity (as specified in 42 CFR 495.102(d)(4)(i)).
- Extreme and Uncontrollable Circumstances (as specified in 42 CFR 495.102(d)(4)(iii)).
- Lack of Control over the Availability of certified EHR technology (as specified in 42 CFR 495.102(d)(4)(iv)(A)).
- Lack of Face-to-Face Patient Interaction (as specified in 42 CFR 495.102(d)(4)(iv)(B)).

We believe that under our proposals for the advancing care information performance category, there may not be sufficient measures applicable and available to MIPS eligible clinicians within the categories above. For these MIPS eligible clinicians, we propose to rely on section 1848(q)(5)(F) of the Act to re-weight the advancing care information performance category to zero.

Sufficient internet access is fundamental to many of the measures proposed for the advancing care information performance category. For example, the ePrescribing measure requires sufficient access to the Internet to transmit prescriptions electronically, and the Secure Messaging measure requires sufficient Internet access to receive and respond to patient messages. These measures may not be applicable to MIPS eligible clinicians who practice in areas with insufficient internet access. We propose to require MIPS eligible clinicians to demonstrate insufficient internet access through an application process in order to be considered for a reweighting of the advancing care information performance category. The application would have to demonstrate that the MIPS eligible clinicians lacked sufficient internet access, during the performance period, and that there were insurmountable barriers to obtaining such infrastructure, such as a high cost of extending the internet infrastructure to their facility.

Extreme and uncontrollable circumstances, such as a natural disaster in which an EHR or practice building are destroyed, can happen at any time and are outside a MIPS eligible clinician's control. If a MIPS eligible clinician's certified EHR technology is unavailable as a result of such circumstances, the measures specified for the advancing care information performance category may not be available for the MIPS eligible clinician to report. We propose that these MIPS eligible clinicians submit an application to include the circumstances by which the EHR technology was unavailable, and for what period of time it was unavailable, to be considered for reweighting of their advancing care information performance category.

In the Stage 2 Final Rule (77 FR 54100) we discussed EPs who practice at multiple locations, and may not have the ability to impact their practices' health IT decisions. We noted the case of surgeons using ambulatory surgery centers or a physician treating patients in a nursing home who does not have any other vested interest in the facility, and may have no influence or control over the health IT decisions of that facility. If MIPS eligible clinicians lack control over the EHR technology in their practice locations, then the measures specified for the advancing care information performance category may not be available to them for reporting. To be considered for a reweighting of the advancing care information performance category, we propose that these MIPS eligible clinicians would need to submit an application demonstrating that a majority (50 percent or more) of their outpatient encounters occur in locations where they have no control over the health IT decisions of the facility, and request their advancing care information performance category score be reweighted to zero. We note that in such cases, the MIPS eligible clinician must have no control over the availability of certified EHR technology. Control does not imply final decision-making authority. For example, we would generally view MIPS eligible clinicians practicing in a large group as having control over the availability of certified EHR technology, because they can influence the group's purchase of certified EHR technology, they may reassign their claims to the group, they may have a partnership/ownership stake in the group, or any payment adjustment would affect the group's earnings and the entire impact of the adjustment would not be borne by the individual MIPS eligible clinician. These MIPS eligible clinicians can influence the availability of certified EHR technology and the group's earnings are directly affected by the payment adjustment. Thus, such MIPS eligible clinicians would not, as a general rule, be viewed as lacking control over the availability of certified EHR technology and would not be eligible for their advancing care information performance category to be reweighted based on their membership in a group practice that has not adopted certified EHR technology.

In the Stage 2 Final Rule (77 FR 54099), we noted the challenges faced by EPs who lack face-to-face interaction with patients (EPs that are non-patient facing), or lack the need to provide follow-up care with patients. Many of the measures proposed under the advancing care information performance category require face-to-face interaction with patients, including all eight of the measures that make up the three performance score objectives (Patient Electronic Access, Coordination of Care Through Patient Engagement and Health Information Exchange). Because these proposed measures rely so heavily on face-to-face patient interactions, we do not believe there would be sufficient measures applicable to non-patient-facing MIPS eligible clinicians under the advancing care information performance category. We propose to automatically reweight the advancing care information performance category to zero for a MIPS eligible clinician who is classified as a non-patient facing MIPS eligible clinician (based on the number of patient-facing encounters billed during a performance period) without requiring an application to be submitted by the MIPS eligible clinician. We refer readers to section II.E.1.b. of this proposed rule for further discussion of non-patient facing MIPS eligible clinicians. We are seeking comment on how the advancing care information performance category could be applied to non-patient facing MIPS eligible clinicians in future years of MIPS, and the types of measures that would be applicable and available to these types of MIPS eligible clinicians.

We propose that all applications for reweighting the advancing care information performance category be submitted by the MIPS eligible clinician or designated group representative in the form and manner specified by CMS. We propose that all applications may be submitted on a rolling basis, but must be received by CMS no later than the close of the submission period for the relevant performance period, or a later date specified by CMS. For example, for the 2017 performance period, applications must be submitted no later than March 31, 2018 (or later date as specified by CMS) to be considered for reweighting the advancing care information performance category for the 2019 MIPS payment year. An application would need to be submitted annually to be considered for reweighting each year.

We invite comments on our proposals.

(iii) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

The definition of a MIPS EP under section 1848(q)(1)(C) of the Act includes certain non-physician practitioners, including Nurse Practitioners (NPs), Physicians Assistants (PAs), Certified Registered Nurse Anesthetists (CRNAs) and Clinical Nurse Specialists (CNSs)). CRNAs and CNSs are not eligible for the incentive payments under Medicare or Medicaid for the adoption and meaningful use of certified EHR technology (sections 1848(o) and 1903(t) of the Act, respectively) or subject to the meaningful use payment adjustment under Medicare (section 1848(a)(7)(A) of the Act), and thus they may have little to no experience with the adoption or use of certified EHR technology. Similarly, NPs and PAs may also lack experience with the adoption or use of certified EHR technology, as they are not subject to the payment adjustment under section 1848(a)(7)(A) of the Act. We further note that only 19,281 NPs and only 1,379 PAs have attested to the Medicaid EHR Incentive Program. Nurse practitioners are eligible for the Medicaid incentive payments under section 1903(t) of the Act, as are PAs practicing in a Federally Qualified Health Center (FQHC) or a rural health clinic (RHC) that is led by a PA, if they meet patient volume requirements and other eligibility criteria.

Because many of these non-physician clinicians are not eligible to participate in the Medicare and/or Medicaid EHR Incentive Program, we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under our proposals for the advancing care information performance category. The low numbers of NPs and PAs who have attested for the Medicaid incentive payments may indicate that EHR Incentive Program measures required to earn the incentive are not applicable or available, and thus would not be applicable or available under the advancing care information performance category. For these reasons, we propose to rely on section 1848(q)(5)(F) of the Act to assign a weight of zero to the advancing care information performance category if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We would assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the advancing care information performance category. We encourage all NPs, PAs, CRNAs, and CNSs to report on these measures to the extent they are applicable and available, however, we understand that some NPs, PAs, CRNAs, and CNSs may choose to accept a weight of zero for this performance category if they are unable to fully report the advancing care information measures. We believe this approach is appropriate for the first MIPS performance period based on the payment consequences associated with reporting, the fact that many of these types of MIPS eligible clinicians may lack experience with EHR use, and our current uncertainty as to whether we have proposed sufficient measures that are applicable and available to these types of MIPS eligible clinicians. We note that we would use the first MIPS performance period to further evaluate the participation of these MIPS eligible clinicians in the advancing care information performance category and would consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

We invite comments on our proposal. We are additionally seeking comment on how the advancing care information performance category could be applied to NPs, PAs, CRNAs, and CNSs in future years of MIPS, and the types of measures that would be applicable and available to these types of MIPS eligible clinicians.

(iv) Medicaid

In the 2015 EHR Incentive Programs Final Rule we adopted an alternate method for demonstrating meaningful use for certain Medicaid EPs that would be available beginning in 2016, for EPs attesting for an EHR reporting period in 2015 (80 FR 62900). Medicaid EPs who previously received an incentive payment under the Medicaid EHR Incentive Program, but failed to meet the eligibility requirements for the program in subsequent years, are permitted to attest using the CMS Registration and Attestation system for the purpose of avoiding the Medicare payment adjustment (80 FR 62900). However, as discussed previously in this proposed rule, section 101(b)(1)(A) of the MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment for Medicare EHR Incentive Program EPs at the end of CY 2018. This means that after the CY 2018 payment adjustment year, there will no longer be a separate Medicare EHR Incentive Program for EPs, and therefore Medicaid EPs who may have used this alternate method for demonstrating meaningful use cannot potentially be subject to a payment adjustment under the Medicare EHR Incentive Program at that time. Accordingly, there will no longer be a need for this alternate method of demonstrating meaningful use after the CY 2018 payment adjustment year.

Similarly, beginning in 2014, states were required to collect, upload and submit attestation data for Medicaid EPs for the purposes of demonstrating meaningful use to avoid the Medicare payment adjustment (80 FR 62915). This form of reporting will also no longer need to continue with the sunset of the meaningful use payment adjustment for Medicare EHR Incentive Program EPs at the end of CY 2018. Accordingly, we are proposing to amend the reporting requirement described at 42 CFR 495.316(g) by adding an ending date such that after the CY 2018 payment adjustment year states would no longer be required to report on meaningful EHR users.

We note that the Medicaid EHR Incentive Program for EPs was not impacted by the MACRA and the requirement under section 1848(q) of the Act to establish the MIPS program. In this rule, we do not propose any changes to the objectives and measures previously established in rulemaking for the Medicaid EHR Incentive Program, and thus EPs participating in that program must continue to report on the objectives and measures under the guidelines and regulations of that program.

Accordingly, reporting on the measures specified for the advancing care information performance category under MIPS cannot be used as a demonstration of meaningful use for the Medicaid EHR Incentive Programs. Similarly, a demonstration of meaningful use in the Medicaid EHR Incentive Programs cannot be used for purposes of reporting under MIPS.

Therefore, MIPS eligible clinicians who are also participating in the Medicaid EHR Incentive Programs must report their data for the advancing care information performance category through the submission methods established for MIPS in order to earn a score for the advancing care information performance category under MIPS and must separately demonstrate meaningful use in their state's Medicaid EHR Incentive Program in order to earn a

Medicaid incentive payment. The Medicaid EHR Incentive Program continues through payment year 2021, with 2016 being the final year an EP can begin receiving incentive payments (§ 495.310(a)(1)(iii)). We solicit comments on alternative reporting or proxies for EPs who provide services to both Medicaid and Medicare patients and are eligible for both MIPS and the Medicaid EHR Incentive Payment.

h. APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

Under section 1848(q)(1)(C)(ii) of the Act, as added by section 101(c)(1) of the MACRA and discussed above in section II.E.3.b. of this proposed rule, Qualifying APM Participants (QPs) are not MIPS eligible clinicians and are thus excluded from MIPS payment adjustments. Partial Qualifying APM Participants (Partial QPs) are also not MIPS eligible clinicians unless they opt to report and be scored under MIPS. All other eligible clinicians participating in APMs are MIPS eligible clinicians and subject to MIPS requirements, including reporting requirements and payment adjustments. However, most current APMs already assess their participants on cost and quality of care and require engagement in certain care improvement activities.

We propose at § 414.1370 to establish a scoring standard for MIPS eligible clinicians participating in certain types of APMs in order to reduce participant reporting burden by eliminating the need for such APM eligible clinicians to submit data for both MIPS and their respective APMs. For purposes of this APM scoring standard, we propose to consider a participant in an APM to be an entity participating in an APM under an agreement with CMS that may either include eligible clinicians or be an eligible clinician and that is directly tied to beneficiary attribution, quality measurement or cost/utilization measurement under the APM. In accordance with section 1848(q)(1)(D)(i) of the Act, we propose to assess the performance of a group of MIPS eligible clinicians in an APM Entity that participates in certain types of APMs based on their collective performance as an APM Entity group, as defined at § 414.1305.

In addition to reducing reporting burden, we seek to ensure that eligible clinicians in APM Entity groups are not assessed in multiple ways on the same performance activities. For instance, performance on the generally applicable resource use measures under MIPS could contribute to upward or downward adjustments to payments under MIPS in a way that is not aligned with the strategy in an ACO initiative for reducing total Medicare costs for a specified population of beneficiaries attributed through the unique ACO initiative's attribution methodology. Depending on the terms of the particular APM, we believe similar misalignments could be common between the MIPS quality and resource use performance categories and the evaluation of quality and resource use in APMs. We believe requiring eligible clinicians in APM Entity groups to submit data, be scored on measures, and be subject to payment adjustments that are not aligned between MIPS and an APM could potentially undermine the validity of testing or performance evaluation under the APM. We also believe imposition of these requirements would result in reporting activity that provides little or no added value to the assessment of eligible clinicians, and could confuse eligible clinicians as to which CMS incentives should take priority over others in designing and implementing care activities.

We are proposing to use the APM scoring standard for MIPS eligible clinicians in APM Entity groups participating in certain APMs that meet the criteria listed below (and are identified as "MIPS APMs" on the CMS Web site). In this section of the rule, we define the proposed criteria for MIPS APMs, the APM scoring standard, the performance period for APM Entity groups, the proposed MIPS scoring methodology for APM Entity groups, and other information related to the APM scoring standard.

(1) Criteria for MIPS APMs

We propose at § 414.1370 to specify that the APM scoring standard under MIPS would only be applicable to certain eligible clinicians participating in MIPS APMs, which we propose to define as APMs (as defined in section II.F.4. of this preamble) that meet the following criteria: (1) APM Entities participate in the APM under an agreement with CMS; (2) the APM Entities include one or more MIPS eligible clinicians on a Participation List; and (3) the APM bases payment incentives on performance (either at the APM Entity or eligible clinician level) on cost/utilization and quality measures. We understand that under some APMs the APM Entity may enter into agreements with clinicians or entities that have supporting or ancillary roles to the APM Entity's performance under the APM, but are not participating under the APM Entity and therefore are not on a Participation List. We would not consider eligible clinicians under such arrangements to be participants for purposes of the APM Entity group to which the APM scoring standard would apply. We understand that this policy would not accommodate certain APMs pursuant to statute or our regulations rather than under an agreement with CMS. We seek comments on how the APM scoring standard should apply to those APMs as well.

The criteria for the identification of MIPS APMs are independent of the criteria for Advanced APM determinations discussed in section II.F.3. of this proposed rule, so a MIPS APM may or may not also be an Advanced APM. As such, it would be possible that an APM meets all three proposed criteria to be a MIPS APM, but does not meet the Advanced APM criteria listed in section II.F.4. Conversely, it would be possible, that an Advanced APM does not meet the criteria listed above because it does not include MIPS eligible clinicians as participants.

The APM scoring standard would not apply to MIPS eligible clinicians involved in APMs that include only facilities as participants (such as the Comprehensive Care for Joint Replacement Model). APMs that do not base payment on cost/utilization and quality measures (such as the Accountable Health Communities Model) would also not meet the proposed criteria for the APM scoring standard. Instead, MIPS eligible clinicians participating in these APMs would need to meet the generally applicable MIPS data submission requirements for the MIPS performance period, and their performance would be assessed using the generally applicable MIPS standards, either as individual eligible clinicians or as a group under MIPS.

As discussed above, the APM scoring standard described in this proposed rule would require MIPS eligible clinicians to report certain data under MIPS regardless of whether they ultimately become QPs or Partial QPs through their participation in Advanced APMs. Although QPs (and Partial QPs who elect not to participate in MIPS) would be excluded from MIPS payment adjustments, we believe it is necessary, for the operational and administrative reasons discussed in section II.F.5.d., to treat these eligible clinicians as MIPS eligible clinicians unless and until the QP or Partial QP determination is made. We believe the proposed APM scoring standard would help to alleviate certain duplicative, unnecessary, or competing data submission requirements for MIPS eligible clinicians participating in MIPS

APMs. However, we are interested in public comments on alternative methods that could reduce MIPS data submission requirements to enable MIPS eligible clinicians participating in Advanced APMs to maximize their focus on the care delivery redesign necessary to succeed within the Advanced APM while maintaining the statutory framework that excludes only certain eligible clinicians from MIPS, and reducing reporting burden on Advanced APM participants.

We invite public comment on alternative MIPS data submission and scoring methods. Specifically, if, during a future performance period, we are able to make QP determinations before MIPS reporting must occur, we seek to attain the least amount of required MIPS data submission while avoiding unnecessary operational complexity.

(2) APM Scoring Standard Performance Period

We propose that the performance period for MIPS eligible clinicians participating in MIPS APMs would match the generally applicable performance period for MIPS proposed in section II.E.4 of this preamble. We propose this policy would apply to all MIPS eligible clinicians participating in MIPS APMs (those that meet the criteria specified in section II.E.5.h.1. of this proposed rule) except for a new MIPS APM for which the first APM performance period begins after the start of the corresponding MIPS performance period. In this instance, the participating MIPS eligible clinicians in the new MIPS APM would submit data to MIPS in the first MIPS performance period for the APM either as individual MIPS eligible clinicians or as a group using one of the MIPS data submission mechanisms for all four performance categories, and report to CMS using the APM scoring standard for subsequent MIPS performance period(s). Additionally, we anticipate that there might be MIPS APMs that would not be able to use the APM scoring standard (even though they met the criteria for the APM scoring standard and were treated as a MIPS APMs in the prior MIPS performance period) in their last year of operation because of technical or resource issues. For example, a MIPS APM in its final year may end earlier than the end of the MIPS performance period (proposed to be December 31). CMS might not have continuing resources dedicated or available to continue to support the MIPS APM activities under the APM scoring standard if the MIPS APM ends during the MIPS performance period. Therefore, if we determine it is not feasible for the MIPS eligible clinicians participating in the APM Entity to report to MIPS using this APM scoring standard in an APM's last year of operation, the MIPS eligible clinicians in the MIPS APM would need to submit data to MIPS either as individual MIPS eligible clinicians or as a group using one of the MIPS data submission mechanisms for the applicable performance period. We propose the eligible clinicians in the MIPS APM would be made aware of this decision in advance of the relevant MIPS performance period.

(3) How the APM Scoring Standard Differs From the Assessment of Groups and Individual MIPS Eligible Clinicians Under MIPS

We believe that establishing an APM scoring standard under MIPS would allow APM Entities and their participating eligible clinicians to focus on the goals and objectives of the APM to improve quality and lower costs of care while avoiding duplicative reporting that would occur as a result of having to submit data to MIPS separately. The APM scoring standard we propose is similar to group assessment under MIPS as described in section II.E.3.d. of this proposed rule, but would differ in one or more of the following ways: (1) Depending on the terms and conditions of the MIPS APM, an APM Entity could be comprised of a sole MIPS eligible clinician (for example, a physician practice with only one eligible clinician could be considered an APM Entity); (2) the APM Entity could include more than one unique TIN, as long as the MIPS eligible clinicians are identified as participants in the APM by their unique APM participant identifiers; (3) the composition of the APM Entity group could include APM participant identifiers with TIN/NPI combinations such that some MIPS eligible clinicians in a TIN are APM participants and other MIPS eligible clinicians in that same TIN are not APM participants. In contrast, assessment as a group under MIPS requires a group to be comprised of at least two MIPS eligible clinicians who have assigned their billing rights to a TIN. It also requires that all MIPS eligible clinicians in the group to use the same TIN.

In addition to the APM Entity group composition being potentially different than that of a group as generally defined under MIPS, we propose for the APM scoring standard that we will generate a MIPS CPS by aggregating all scores for MIPS eligible clinicians in the APM Entity that is participating in the MIPS APM to the level of the APM Entity. We believe that aggregating the MIPS performance category scores at the level of the APM Entity is more meaningful to, and appropriate for, these MIPS eligible clinicians because they have elected to participate in an APM and collectively focus on care transformation activities to improve the quality of care.

Further, we propose below that, depending on the type of MIPS APM, the weights associated with performance categories may be different than the generally applicable weights for MIPS eligible clinicians. The weights assigned to the MIPS performance categories under the APM scoring standard for MIPS eligible clinicians who are participating in a MIPS APM may be different from the performance category weights for MIPs eligible clinicians not participating in a MIPS APM for the same performance period. For example, we propose below that under the APM scoring standard, the weight for the resource use performance category will be zero. We also propose that for certain MIPS APMs, the weight for the quality performance category will be zero for the 2019 payment year. Where the weight for the performance category is zero, neither the APM Entity nor the MIPS eligible clinicians in the MIPS APM would need to report data in these categories, and we would redistribute the weights for the quality and resource use performance categories to the CPIA and advancing care information performance categories to maintain a CPS of 100 percent.

In order to implement certain elements of the APM scoring standard, we would need to use the Shared Savings Program (section 1899 of the Act) and CMS Innovation Center (section 1115A of the Act) authorities to waive specific statutory provisions related to MIPS reporting and scoring. Section 1899(f) of the Act authorizes waivers of title XVIII requirements as may be necessary to carry out the Shared Savings Program, and section 1115A(d)(1) of Act authorizes waivers of title XVIII requirements as may be necessary solely for purposes of testing models under section 1115A of the Act. In each section below in which we propose scoring methodologies and waivers to enable the proposed approaches, we describe how the use of waivers is necessary under the respective waiver authority standards. The underlying purpose of APMs is for CMS to pay for care in ways that are unique from fee-for-service payment and to test new ways of measuring and assessing performance. If the data submission requirements and associated adjustments under MIPS are not aligned with APM-specific goals and incentives, the participants receive conflicting messages from CMS on priorities, which could create uncertainty and severely degrade our ability to evaluate the impact of any particular APM on the overall cost and quality of care. Therefore, we believe that, for reasons stated in this section, certain waivers are necessary for testing and operating APMs and for maintaining the integrity of our evaluation of those APMs.

We note that for at least the first performance year, we do not anticipate that any APMs not authorized under sections 1115A or 1899 of the Act would meet the criteria to be MIPS APMs. In the event that we do anticipate other Federal demonstrations will become MIPS APMs, we will address MIPS scoring for participating eligible clinicians in future rulemaking.

(4) APM Participant Identifier and Participant Database

To ensure we have accurately captured performance data for all of the MIPS eligible clinicians that are participating in an APM, we would establish and maintain an APM participant database that will include all of the MIPS eligible clinicians who are part of the APM Entity. We would establish this database to track participation in all APMs, in addition to specifically tracking participation in MIPS APMs and Advanced APMs. We propose that each APM Entity be identified in the MIPS program by a unique APM Entity identifier. We also propose in section II.E.2.b. that the unique APM participant identifier for a MIPS eligible clinician would be a combination of four identifiers including: (1) APM identifier (established for the APM by CMS; for example, XXXXXX); (2) APM Entity identifier (established for the APM by CMS; for example, AA00001111); (3) the eligible clinician's billing TIN (for example, XXXXXXXXX); and (4) NPI (for example, 1111111111). For example, this APM participant identifier for the MIPS eligible clinician in this case would be APM XXXXXX, APM Entity AA00001111, TIN–XXXXXXXXX, NPI–11111111111. The use of the APM participant identifier will allow CMS to identify all MIPS eligible clinicians participating in an APM Entity, including instances when the MIPS eligible clinicians use a billing TIN that is shared with MIPS eligible clinicians who are not participating in the APM Entity. We would plan to communicate to each APM Entity the MIPS eligible clinicians who are included in the APM Entity group in advance of the applicable MIPS data submission deadline for the MIPS performance period.

Under the Shared Savings Program, each ACO is formed by a collection of Medicare-enrolled TINs (ACO participants). Pursuant to our regulation at 42 CFR 425.118, all Medicare enrolled individuals and entities that have reassigned their rights to receive Medicare payment to the TIN of the ACO participant must agree to participate in the ACO and comply with the requirements of the Shared Savings Program. Because all providers and suppliers that bill through the TIN of an ACO participant are required to agree to participate in the ACO, all MIPS eligible clinicians that bill through the TIN of an ACO participant are considered to be participating in the ACO. For purposes of the APM scoring standard, the ACO would be the APM Entity. The Shared Savings Program has established criteria for determining the list of eligible clinicians participating under the ACO, and we would use the same criteria for determining the list of MIPS eligible clinicians included in the APM Entity group for purposes of the APM scoring standard.

We recognize that there may be scenarios in which MIPS eligible clinicians may change TINs, use more than one TIN for billing Medicare, change their APM participation status, and/or change other practice affiliations during a performance period. Therefore, we propose that only those MIPS eligible clinicians who are listed as participants in the APM Entity in a MIPS APM on December 31 (the last day of the proposed performance period) would be considered part of the APM Entity group for purposes of the APM scoring standard. Consequently, MIPS eligible clinicians who are not listed as participants of an APM Entity in a MIPS APM at the end of the performance period would need to submit data to MIPS through one of the MIPS data submission mechanisms and would have their performance assessed either as individual MIPS eligible clinicians or as a group for all four performance categories. For example, a MIPS eligible clinician who participates in the APM Entity on January 1, 2017 and leaves the APM Entity on June 15, 2017 would need to submit data to MIPS using one of the MIPS data submission mechanisms and would have their performance assessed either as individual MIPS eligible clinicians or as a group. This approach for defining the applicable group of MIPS eligible clinicians is consistent with our proposal for identifying eligible clinician groups for purposes of QP determinations outlined in section II.F.5.b. of this proposed rule; the group of eligible clinicians CMS uses for purposes of a QP determination would be the same as that used for the APM scoring standard. This would be an annual process for each MIPS performance period. We propose to calculate one MIPS CPS for each APM Entity group, and that MIPS CPS would be applied to all MIPS eligible clinicians in the group. As previously explained in section II.E.7. of this proposed rule, the MIPS payment adjustment would be applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(5) MIPS Eligible Clinicians Not Participating in a MIPS APM

The APM Entity group used for purposes of the APM scoring standard would be the same APM Entity group used for QP determinations under section II.F.5 of this proposed rule, except in the instances of APMs that do not meet the criteria to be MIPS APMs, as discussed in section II.E.5.h.(1) of this proposed rule. Examples of APMs that would not meet criteria to be MIPS APMs are those that do not have MIPS eligible clinicians as participants under the APM, or do not tie payment to cost/utilization and quality measures. We propose that the APM scoring standard would not apply to MIPS eligible clinicians participating in APMs that are not MIPS APMs. MIPS eligible clinicians who participate in an APM that is not a MIPS APM, would submit data to MIPS and have their performance assessed either as an individual MIPS eligible clinician or group as described in section II.E.2. of this proposed rule. Some APMs may involve certain types of MIPS eligible clinicians that are affiliated with an APM Entity but not included in the APM Entity group because they are not participants of the APM Entity. We propose that even if the APM meets the criteria to be a MIPS APM, MIPS eligible clinicians who are not included in the list of participants would not be considered part of the APM Entity group for purposes of the APM scoring standard. For instance, MIPS eligible clinicians in the Comprehensive Care for Joint Replacement Model might be involved in the APM through a business arrangement with the APM Entity (the inpatient hospital) but are not directly tied to beneficiary attribution, quality measurement, or care improvement activities under the APM. Additionally, we propose that if a MIPS eligible clinician participates in an APM Entity during the MIPS performance period but is no longer a participant in the APM Entity group on the last day of the performance period, the MIPS eligible clinician must submit either individual or group level data to MIPS. CMS will publish the list of MIPS APMs prior to the beginning of the MIPS performance period on the CMS Web site.

(6) APM Entity Group Scoring for the MIPS Performance Categories

As mentioned previously, section 1848(q)(3)(A) of the Act requires the Secretary to establish performance standards for the measures and activities under the following performance categories: (1) Quality; (2) resource use; (3) clinical practice improvement activities; and (4) advancing care information. We propose at § 414.1370 to calculate one CPS that is applied to the billing TIN/NPI combination of each MIPS eligible clinician in the APM Entity group. Therefore, each APM Entity group (for example, the MIPS eligible clinicians in a Shared Savings Program ACO or an Oncology Care Model practice) would receive a score for each of the four performance categories according to the proposals described in this section of the proposed rule, and we would calculate one CPS for the group. The APM Entity group score would be applied to each MIPS eligible clinician in the group, and subsequently used to develop the MIPS payment adjustment that is applicable for each MIPS eligible clinician in the group. Thus the APM Entity group score and the participating MIPS eligible clinician score are the same. For example, in the Shared Savings Program, the MIPS eligible clinicians in each ACO would be an APM Entity group. That group would receive a single CPS that would be applied to each of its participating MIPS eligible clinicians. Similarly, in the Oncology Care Model, the MIPS eligible clinicians in each oncology practice would be an APM Entity group. That group would receive a single CPS that would be applied to each of the MIPS eligible clinicians in the group. We note that this APM Entity group CPS is not used to evaluate eligible clinicians or the APM Entity for purposes of incentives within the APM, shared savings payments, or other potential payments under the APM, and we currently do not foresee APMs that would use the CPS for purposes of evaluation within the APM. Rather the APM Entity group CPS would be used only for the purposes of the APM scoring standard under MIPS for the first MIPS performance period. As proposed in this rule, all MIPS eligible clinicians listed as participating in the APM Entity on the last day of the performance period would be part of the APM Entity group and thus receive the same CPS. It should be noted that although we propose that the APM scoring standard only applies to participants in MIPS APMs, MIPS eligible clinicians that participate in an APM (including but not limited to a MIPS APM) and submit either individual or group level data to MIPS may earn a minimum score of 50 percent of the highest potential CPIA performance category score as long as such MIPS eligible clinicians are on the list of participants for an APM and are identifiable by the APM participant identifier.

Several commenters on the MIPS and APMs RFI suggested, and we generally agree, that MIPS eligible clinicians who collaborate under an APM Entity to accomplish the APM's goals should be treated as a group under MIPS and receive the same CPS. Furthermore, we want to avoid situations in which different MIPS eligible clinicians in the same APM Entity group receive different MIPS scores. APM Entities have a goal of collective success under the terms of the APM, so having a variety of differing MIPS adjustments for eligible clinicians within that collective unit would undermine the intent behind the APM to test a departure from a purely fee-for-service system based on independent clinician activity. Lastly, we believe that measurement of the performance for MIPS at the APM Entity level for eligible clinicians participating in MIPS APMs will result in more statistically valid performance scores for these eligible clinicians because the scores are aggregated to represent a larger group of MIPS eligible clinicians.

We propose, for the first MIPS performance period, a specific scoring and reporting approach for the MIPS eligible clinicians participating in MIPS APMs, which would include the Shared Savings Program, the Next Generation ACO Model, and other APMs that meet the criteria proposed above for a MIPS APM. Specifically, we propose that APM quality measure data submitted through the CMS Web Interface by ACOs participating in the Shared Savings Program and the Next Generation ACO Model would be used to evaluate performance for the MIPS quality performance category. We believe this is appropriate because all MIPS eligible clinicians that use the CMS Web Interface as their quality measure submission mechanism, *e.g.*, MIPS eligible clinicians that report as a group and MIPS APM eligible clinicians that report as an APM Entity group, submit data on the same quality measures. Both the Shared Savings Program and the Next Generation ACO Model use additional quality measures for the purpose of APM performance assessment, but only the measures submitted to the CMS Web Interface would be used to evaluate performance for the MIPS quality performance category. Therefore, other measures that are required by the APM to assess APM quality performance will continue to be used for APM performance assessment only and not included in the MIPS quality performance category scoring. We also propose that MIPS eligible clinicians participating in MIPS APMs that do not use the CMS Web Interface as the mechanism for submitting APM quality data would not submit quality measure data to MIPS for the MIPS quality performance category until the second MIPS performance period (2018). In this section of the rule, we describe the APM Entity data submission requirements and propose a scoring approach for each of the MIPS performance categories for specific MIPS APMs (the Shared Savings Program, Next Generation ACO Model, and all other MIPS APMs).

(7) Shared Savings Program—Quality Performance Category Scoring Under the APM Scoring Standard

Beginning with the first MIPS performance period all Shared Savings Program ACOs would submit their quality measures to MIPS using the CMS Web Interface through the same process that they use to report to the Shared Savings Program and be scored as they normally would under Shared Savings Program rules. Shared Savings Program ACOs have used the CMS Web Interface for submitting their quality measures since the program's inception, making this a familiar data submission process. We also propose that the Shared Savings Program ACO quality measure data that is submitted through the CMS Web Interface will be submitted only once but will be used for two purposes. The Shared Savings Program quality measure data reported to the CMS Web Interface would be used by CMS to calculate the MIPS quality performance category score at the APM Entity group (ACO) level. The Shared Savings Program quality performance data that is not submitted to the CMS Web Interface, for example the CAHPS survey and other claims measures would not be included in the MIPS APM quality performance category score. We believe this will reduce the reporting burden for Shared Savings Program MIPS eligible clinicians by requiring quality measure data to be submitted only once and used for both programs. The MIPS quality performance category requirements and performance benchmarks for quality measures submitted via the CMS Web Interface would be used to determine the MIPS quality performance category score at the ACO level for the APM Entity group.

We believe that no waivers are necessary here because the quality measures submitted via the CMS Web Interface under the Shared Savings Program are also MIPS quality measures and will be scored under MIPS performance standards. In the event that Shared Savings Program quality measures depart from MIPS measures in the future, we will address such changes including whether further waivers are necessary at such a time in future rulemaking.

(8) Shared Savings Program—Resource Use Performance Category Scoring Under the APM Scoring Standard

We propose that for the first MIPS performance period, we will not assess MIPS eligible clinicians participating in the Shared Savings Program (the MIPS APM) under the resource use performance category. We propose this approach because: (1) Eligible clinicians participating in the Shared Savings Program are already subject to cost and utilization performance assessments under the APM; (2) the Shared Savings Program measures resource use in terms of an objective, absolute total cost of care expenditure benchmark for a population of attributed beneficiaries, and participating ACOs may share savings and/or losses based on that standard, whereas the MIPS resource use measures are relative measures such that clinicians are graded relative to their peers, and therefore different than assessing total cost of care for a population of attributed beneficiaries; and (3) the beneficiary attribution methodologies for measuring resource use under the Shared Savings Program and MIPS differ, leading to an unpredictable degree of overlap (for eligible clinicians and for CMS) between the sets of beneficiaries for which eligible clinicians would be responsible that would vary based on unique APM Entity characteristics such as which and how many TINs comprise an ACO. We believe that with an APM Entity's finite resource for engaging in efforts to improve quality and lower costs for a specified beneficiary population, the population identified through an APM must take priority to ensure that the goals and program evaluation associated with the APM are as clear and free of confounding factors as possible. The potential for different, conflicting results across Shared Savings Program and MIPS assessments—due to the differences in attribution, the inclusion in MIPS of episode-based measures that do not reflect the total cost of care, and the objective versus relative assessment factors listed above—creates uncertainty for eligible clinicians who are attempting to strategically transform their respective practices and succeed under the terms of the Shared Savings Program.

For example, Shared Savings Program ACOs are held accountable for expenditure benchmarks that reflect the total Medicare Parts A and B spending for their assigned beneficiaries, whereas many of the proposed MIPS resource use measures focus on spending for particular episodes of care or clinical conditions. For the reasons stated above, we consider it a programmatic necessity that the Shared Savings Program has the ability to structure its own measurement and payment for performance on total cost of care independent from other incentive programs such as the resource use performance category under MIPS. Thus, we propose to reduce the MIPS resource use performance category weight to zero for all MIPS eligible clinicians in APM Entities participating in the Shared Savings Program. Accordingly, under section 1899(f) of the Act, we propose to waive—for MIPS eligible clinicians participating in the Shared Savings Program—the requirement under section 1848(q)(5)(E)(i)(II) of the Act that specifies the scoring weight for the resource use performance category. With the proposed reduction of the resource use performance category weight to zero, we believe it would be unnecessary specify and use resource use measures in determining the MIPS CPS for these MIPS eligible clinicians. Therefore, under section 1899(f) of the Act, we propose to waive—for MIPS eligible clinicians participating in the Shared Savings Program—the requirements under sections 1848(q)(2)(B)(ii) and 1848(q)(2)(A)(ii) of the Act to specify and use, respectively, resource use measures in calculating the MIPS CPS for such MIPS eligible clinicians.

Given the proposal to waive requirements under section 1848(q)(5)(E)(i)(II) of the Act in order to reduce the weight of the resource use performance category to zero, we must subsequently specify how that weight would be redistributed among the remaining performance categories in order to maintain a total weight of 100 percent. We propose to redistribute the resource use performance category weight to both the CPIA and advancing care information performance categories as specified in Table 12. The MIPS resource use performance category is proposed to have a weight of 10 percent for the first performance period. Because the MIPS quality performance category bears a relatively higher weight than the other three MIPS performance categories, and its weight is scheduled to be reduced from 50 to 30 percent over time, we propose to evenly redistribute the 10 percent resource use performance category weight to the CPIA and advancing care information performance categories so that the distribution does not change the relative weight of the quality performance category in the opposite direction of its future state. The redistributed resource use performance category weight of 10 percent would result in a 5 percentage point increase (from 15 to 20 percent) for the CPIA performance category and a 5 percentage point increase (from 25 to 30 percent) for the advancing care information performance category. We invite comments on the proposed weights and specifically, whether we should increase the MIPS quality performance category weight.

We understand that as the MIPS resource use performance category evolves over time, there might be greater potential for alignment and less potential duplication or conflict with MIPS resource use measurement for MIPS eligible clinicians participating in APMs such as the Shared Savings Program. We will continue to monitor and consider how we might incorporate an assessment in the MIPS resource use performance category into the APM scoring standard for MIPS eligible clinicians participating in the Shared Savings Program. We also understand that reducing the resource use performance category weight to zero and redistributing the weight to the CPIA and advancing care information performance categories could, to the extent that CPIA and advancing care information scores are higher than the scores these MIPS eligible clinicians would have received under resource use, result in higher average scores for MIPS eligible clinicians participating in the Shared Savings Program. We seek comment on the possibility of assigning a neutral score to the Shared Savings Program APM Entity groups for the resource use performance category to moderate MIPS composite performance scores for APM Entities participating in the Shared Savings Program. We also generally seek comment on our proposed policy, and on whether and how we should incorporate the resource use performance category into the APM scoring standard under MIPS for eligible clinicians participating in the Shared Savings Program for future years.

(9) Shared Savings Program—CPIA and Advancing Care Information Performance Category Scoring Under the APM Scoring Standard

We propose that MIPS eligible clinicians participating in the Shared Savings Program would submit data for the MIPS CPIA and advancing care information performance categories through their respective ACO participant billing TINs independent of the Shared Savings Program ACO. Pursuant to section 1848(q)(5)(C)(ii) of the Act, all ACO participant group billing TINs would receive a minimum of one half of the highest possible score for the CPIA performance category. Additionally, pursuant to section 1848(q)(5)(C)(i) of the Act, any ACO participant TIN that is determined to be a patient-centered medical home or comparable specialty practice will receive the highest potential score for the CPIA performance category. The scores from all of the ACO participant billing TINs would be averaged to a weighted mean MIPS APM Entity group level score. We propose to use a weighted mean in computing the overall CPIA and advancing care information quality performance category score in order to account for difference in the size of each TIN and to allow each TIN to contribute to the overall score based on its size. Then all MIPS eligible clinicians in the APM Entity group, as identified by their APM participant identifiers, would receive that APM Entity score. The weights used for each ACO participant billing TIN would be the number of MIPS eligible clinicians in that TIN. Because all providers and suppliers that bill through the TIN of an ACO participant are required to agree to participate in the ACO, all MIPS eligible clinicians that bill through the TIN of an ACO participant are considered to be participating in the ACO. Any Shared Savings Program ACO participant billing TIN that does not submit data for the MIPS CPIA and/or advancing care information performance categories would contribute a score of zero for each performance category for which it does not report; and that score would be incorporated into the resulting weighted average score for the Shared Savings Program ACO. All MIPS eligible clinicians in the ACO (the APM Entity group) would receive the same score that is calculated at the ACO level (the APM Entity).

TABLE 11: Example of MIPS Scoring for an APM Entity Group in the Shared Savings Program for CPIA and Advancing Care Information

	CPIA	Advancing Care Information	# MIPS Eligible Clinicians (weight)	Weighted CPIA (CPIA x Eligible Clinicians)	Weighted Advancing Care Information (Advancing Care Information x Eligible Clinicians)
TIN A	100	95	250	25000	23750
TIN B	(TIN did not report) 0	90	100	0	9000
TIN C	95	65	150	14250	9750
Total			500	39250	42500
Aggregate APM Entity Score (Total/500)				78.5	85

In this example, each eligible clinician participating in the APM Entity (Shared Savings Program ACO) would receive a CPIA performance category score of 78.5 and an advancing care information performance category score of 85. We recognize that the Shared Savings Program eligible clinicians participate as a complete TIN because all of the eligible clinicians that have reassigned their Medicare billing rights to the TIN of an ACO participant must agree to participate in the Shared Savings Program. This is different from other APMs, which may include APM Entity groups with eligible clinicians who share a billing TIN with other eligible clinicians who do not participate in the APM Entity. We seek comment on a possible alternative approach in which CPIA and advancing care information performance category scores would be applied to all MIPS eligible clinicians at the individual billing TIN level, as opposed to aggregated to the ACO level, for Shared Savings Program participants. If MIPS APM scores were applied to each TIN in an ACO at the TIN level, we would also likely need to permit those TINs to make the Partial QP election, as discussed elsewhere in this proposed rule, at the TIN level. We propose that under the APM scoring standard, the ACO-level APM Entity group score would be applied to each participating MIPS eligible clinician to determine the MIPS payment adjustment. We believe calculating the score at the APM Entity level mirrors the way APM participants are assessed for their shared savings and other incentive payments in the APM, but we understand there may be reasons why a group TIN, particularly one that believes it would achieve a higher score than the weighted average APM Entity level score, would prefer to be scored in the CPIA and advancing care information performance categories at the level of the group billing TIN rather than the ACO (APM Entity level). Therefore, we seek comment as to whether Shared Savings Program ACO eligible clinicians should be scored at the ACO level or the group billing TIN level for the CPIA and advancing care information performance categories. In

Table 12, we provide a summary of the proposed MIPS data submission requirements and scoring under the APM scoring standard for MIPS eligible clinicians participating in a Shared Savings Program ACO.

TABLE 12: MIPS Data Submission, Performance Category Score and Performance Category Weight for MIPS eligible clinicians participating in the Shared Savings Program-2017 Performance Period for the 2019 Payment Adjustment

MIPS Performance Category	Alternative Payment Entity Data Submission Requirement	Performance Score	Performance Category Weight
Quality	Shared Savings Program ACOs submit quality measures to the CMS Web Interface on behalf of their participating MIPS eligible clinicians.	The MIPS quality performance category requirements and benchmarks will be used to determine the MIPS quality performance category score at the ACO level.	50%
Resource Use	The Shared Savings Program ACO participating MIPS eligible clinicians would not be assessed on Resource Use.	N/A	0%
Clinical Improvement Performance Activities	All MIPS eligible clinicians participating in the APM Entity group submit under this category according to the MIPS requirements and have their CPIA performance assessed as a group through their billing TINs associated with the ACO.	All ACO participant group billing TINs will receive a minimum of one half of the total possible points. Additionally, any ACO participant TIN that is determined to be a patient-centered medical home or comparable specialty practice will receive the highest potential score. All of the ACO participant TIN scores for MIPS eligible clinicians in the APM Entity group will be aggregated, weighted and averaged to yield one ACO level score.	20%
Advancing Care Information	All MIPS eligible clinicians participating in the APM Entity group submit under this category according to the MIPS requirements and have their performance assessed as a group through their billing TINs associated with the ACO.	All of the ACO participant group billing TIN scores will be aggregated as a weighted average to yield one ACO group score.	30%

(10) Next Generation ACO Model—Quality Performance Category Scoring Under the APM Scoring Standard

Beginning with the first MIPS performance period, all Next Generation ACO Model ACOs would submit their ACO quality measures to MIPS using the CMS Web Interface through the same process that they use to report to the Next Generation ACO Model and be scored as they normally would under Next Generation ACO Model rules. Next Generation ACO Model ACOs will have used the CMS Web Interface for submitting their quality measures since the model's inception and would most likely continue to use the CMS Web Interface as the submission method in future years. We also propose that the Next Generation ACO Model quality measure data that is submitted through the CMS Web Interface will be submitted only once but will be used for two purposes. The Next Generation ACO Model quality measure data reported to the CMS Web Interface would be used by CMS to calculate the MIPS APM quality performance score. The MIPS quality performance category requirements and performance benchmarks for reporting quality measures via the CMS Web Interface would be used to determine the MIPS quality performance category score at the ACO level for the APM Entity group. The Next Generation ACO Model quality performance data that is not submitted to the CMS Web Interface, for example the CAHPS survey and other claims measures would not be included in the MIPS APM quality performance score. The MIPS APM quality performance category score would be calculated using only quality measure data submitted through the CMS Web Interface, while the quality reporting requirements and performance benchmarks calculated by the Next

Generation ACO Model would continue to be used to assess the ACO under the APM specific requirements. We believe this approach would reduce the reporting burden to Next Generation ACO Model participants by requiring quality measure data to be submitted only once and used for both MIPS and the Next Generation ACO Model.

We believe that no waivers are necessary here because the quality measures submitted via the CMS Web Interface under the Next Generation ACO Model are MIPS quality measures and will be scored under MIPS performance standards. In the event that Next Generation ACO Model quality measures depart from MIPS measures in the future, we will address such changes, including whether further waivers are necessary, at such a time in future rulemaking.

(11) Next Generation ACO Model—Resource Use Performance Category Scoring Under the APM Scoring Standard

We propose that for the first MIPS performance period, we will not assess MIPS eligible clinicians in the Next Generation ACO Model participating in the MIPS APM under the resource use performance category. We propose this approach because: (1) MIPS eligible clinicians participating in the Next Generation ACO Model are already subject to cost and utilization performance assessments under the APM; (2) the Next Generation ACO Model measures resource use in terms of an objective, absolute total cost of care expenditure benchmark for a population of attributed beneficiaries, and participating ACOs may share savings and/or losses based on that standard, whereas the MIPS resource use measures are relative measures such that clinicians are graded relative to their peers and therefore different than assessing total cost of care for a population of attributed beneficiaries; and (3) the beneficiary attribution methodologies for measuring resource use under the Next Generation ACO Model and MIPS differ, leading to an unpredictable degree of overlap (for eligible clinicians and for CMS) between the sets of beneficiaries for which eligible clinicians would be responsible that would vary based on unique APM Entity characteristics such as which and how many eligible clinicians comprise an ACO. We believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population, the population identified through the Next Generation ACO Model must take priority to ensure that the goals and model evaluation associated with the APM are as clear and free of confounding factors as possible. The potential for different, conflicting results across the Next Generation ACO Model and MIPS assessments—due to the differences in attribution, the inclusion in MIPS of episode-based measures that do not reflect the total cost of care, and the objective versus relative assessment factors listed above—creates uncertainty for eligible clinicians who are attempting to strategically transform their respective practices and succeed under the terms of the Next Generation ACO Model. For example, Next Generation ACOs are held accountable for expenditure benchmarks that reflect the total Medicare Parts A and B spending for their attributed beneficiaries, whereas many of the proposed MIPS resource use measures focus on spending for particular episodes of care or clinical conditions. For all the reasons stated above, we propose to reduce the MIPS resource use performance category weight to zero for all MIPS eligible clinicians participating in the Next Generation ACO Model. Accordingly, under section 1115A(d)(1) of the Act, we propose to waive—for MIPS eligible clinicians participating in the Next Generation ACO Model—the requirement under section 1848(q)(5)(E)(i)(II) of the Act that specifies the scoring weight for the resource use performance category. With the proposed reduction of the resource use performance category weight to zero, we believe it would be unnecessary to specify and use resource use measures in determining the MIPS CPS for these MIPS eligible clinicians. Therefore, under section 1115A(d)(1) of the Act, we propose to waive—for MIPS eligible clinicians participating in the Next Generation ACO Model—the requirements under sections 1848(q)(2)(B)(ii) and 1848(q)(2)(A)(ii) of the Act to specify and use, respectively, resource use measures in calculating the MIPS CPS for such eligible clinicians.

Given the proposal to waive requirements under section 1848(q)(5)(E) of the Act in order to reduce the weight of the resource use performance category to zero, we must subsequently specify how that weight would be redistributed among the remaining performance categories in order to maintain a total weight of 100 percent. We propose to redistribute the resource use performance category weight to both the CPIA and advancing care information performance categories as specified in Table 13. The MIPS resource use performance category is proposed to have a weight of 10 percent. Because the MIPS quality performance category bears a relatively higher weight than the other three MIPS performance categories and its weight is scheduled to be reduced from 50 to 30 percent over time, we propose to evenly redistribute the 10 percent resource use weight to the CPIA and advancing care information performance categories so that the distribution does not change the relative weight of the quality performance category in the opposite direction of its future state. The redistributed resource use performance category weight of 10 percent would result in a 5 percentage point increase (from 15 to 20 percent) for the CPIA performance category and a 5 percentage point increase (from 25 to 30 percent) for the advancing care information performance category. We invite comments on the proposed redistributed weights and specifically on whether we should also increase the MIPS quality performance category weight.

We understand that as the MIPS resource use performance category evolves over time, there might be greater potential for alignment and less potential duplication or conflict with MIPS resource use measurement for MIPS eligible clinicians participating in MIPS APMs such as the Next Generation ACO Model. We will continue to monitor and consider how we might incorporate an assessment in the MIPS resource use performance category into the APM scoring standard for the Next Generation ACO Model. We also understand that reducing the resource use weight to zero and redistributing the weight to the CPIA and advancing care information performance categories could, to the extent that CPIA and advancing care information scores are higher than the scores MIPS eligible clinicians would have received under resource use, result in higher average scores for MIPS eligible clinicians in APM Entity groups participating in the Next Generation ACO Model. We seek comment on the possible alternative of assigning a neutral score to APM Entity groups (ACOs) participating in the Next Generation ACO model for the resource use performance category in order to moderate APM Entity scores. We also generally seek comment on our proposed policy, and on whether and how we should incorporate the resource use performance category into the APM scoring standard for MIPS eligible clinicians in APM Entity groups participating in the Next Generation ACO model for future years.

(12) Next Generation ACO Model—CPIA and Advancing Care Information Performance Category Scoring Under the APM Scoring Standard

We propose that all MIPS eligible clinicians participating in the Next Generation ACO Model would submit data for the CPIA and advancing care information performance categories. Eligible clinicians in the Next Generation ACO Model may belong to a billing TIN that includes non-participating APM eligible clinicians. Therefore for both CPIA and the advancing care information performance category, we propose that these MIPS eligible clinicians would submit individual level data to MIPS and not group level data.

For both the CPIA and advancing care information performance categories, the scores from all of the individual MIPS eligible clinicians in the APM Entity group would be aggregated to the APM Entity level and averaged for a mean score. Any individual MIPS eligible clinicians that do not report the CPIA or advancing care information performance category would contribute a score of zero for that performance category in the calculation of the APM Entity score. All MIPS eligible clinicians in the APM Entity group would receive the same APM Entity score.

As noted above, because the MIPS quality performance category bears a relatively higher weight than the other three MIPS performance categories, we propose to evenly redistribute the 10 percent resource use performance category weight to the CPIA and advancing care information performance categories. Section 1848(q)(5)(C)(i) of the Act requires that MIPS eligible clinicians who are in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, with respect to a performance period shall be given the highest potential score for the CPIA performance category. Accordingly, a MIPS eligible clinician participating in an APM Entity that meets the definition of a patient-centered medical home or comparable specialty practice, as discussed in section II.E.5.f. of this proposed rule, will receive the highest potential score. Additionally, section 1848(q)(5)(C)(ii) of the Act requires that MIPS eligible clinicians participating in APMs that are not patient-centered medical homes for a performance period shall earn a minimum score of one-half of the highest potential score for CPIA.

For the APM scoring standard for the first MIPS performance period, we propose to weight the CPIA and advancing care information performance categories for the Next Generation ACO Model in the same way that we propose to weight those categories for the Shared Savings Program: 20 percent and 30 percent for CPIA and advancing care information, respectively. We seek comment on our proposals for reporting and scoring the CPIA and advancing care information performance categories under the APM scoring standard. In particular, we seek comment on the appropriate weight distributions in the first year.

In Table 13, we provide a summary of the proposed MIPS data submission and scoring under the APM scoring standard for MIPS eligible clinicians participating in a Next Generation ACO.

TABLE 13: MIPS Data Submission, Performance Category Score and Performance Category Weight for eligible clinicians participating in the Next Generation ACO Model – 2017 Performance Period for the 2019 Payment Adjustment

MIPS Performance Category	Alternative Payment Entity Reporting Requirement	Performance Score	Performance Category Weight
Quality	ACOs submit to the CMS Web Interface on behalf of their participating MIPS eligible clinicians.	The MIPS quality performance category requirements and benchmarks will be used to develop the ACO MIPS quality score.	50%
Resource Use	The ACO and its participating MIPS eligible clinicians are not assessed on resource use.	N/A	0%
Clinical Improvement Performance Activities	All MIPS eligible clinicians in the APM Entity group submit individual level data for this category.	All MIPS eligible clinicians in the APM Entity group will receive a minimum of one half of the total possible points. Additionally, any MIPS eligible clinician that participates in a patient-centered medical home or comparable specialty practice will receive the highest potential score. All of the MIPS eligible clinician scores will be aggregated and averaged to yield one ACO score. An ACO eligible clinician that does not report this performance category would contribute a score of zero.	20%
Advancing Care Information	All MIPS eligible clinicians in the APM Entity group submit individual level data for this category	All of the MIPS eligible clinician scores will be aggregated and averaged to yield one ACO score. An ACO eligible clinician that does not report this performance category would contribute a score of zero.	30%

(13) MIPS APMs Other Than the Shared Savings Program and the Next Generation ACO Model—Quality Performance Category Scoring Under the APM Scoring Standard

For MIPS APMs other than the Shared Savings Program and the Next Generation ACO Model, we propose that eligible clinicians or APM Entities would submit APM quality measures under their respective MIPS APM as usual, and those eligible clinicians or APM Entities would not also be required to submit quality information under MIPS. Current MIPS APMs have requirements regarding the number of quality measures, measure specifications, as well as the measure reporting method(s) and frequency of reporting, and have an established mechanism for submission of these measures to CMS. We believe there are operational considerations and constraints that would prevent us from being able to use the quality measure data from some MIPS APMs for the purpose of satisfying the MIPS data submission requirements for the quality performance category in the first performance period. For example, some current APMs use a quality measure data collection system or vehicle that is separate and distinct from the MIPS systems. We do not believe there is sufficient time to adequately implement changes to the current APM quality measure data collection timelines and infrastructure to conduct a smooth hand-off to the MIPS system that would enable use of APM quality measure data to satisfy the MIPS quality performance category requirements in the first MIPS performance period. As we have noted, we are concerned about subjecting MIPS eligible clinicians who participate in MIPS APMs to multiple performance assessments—under MIPS and under the APMs—that are not necessarily aligned and that could potentially undermine the validity of testing or performance evaluation under the APM. As stated previously, our goal is to reduce MIPS eligible clinician reporting burden by not requiring APM participants to report quality data twice to CMS, and to avoid misaligned performance incentives. Therefore, we propose that, for the first MIPS performance period only, for MIPS eligible clinicians participating in APM Entity groups in MIPS APMs (other than the Shared Savings Program or the Next Generation ACO Model), we would reduce the weight for the quality performance category to zero. We believe it is necessary to do this because CMS requires additional time to make adjustments in systems and processes related to the submission and collection of APM quality measures in order to align APM quality measures with the MIPS, and ensure APM quality measure data can be submitted in a time and in a manner sufficient for use in assessing quality performance under MIPS and under the APM. Additionally, due to the implementation of a new program that does not account for non-MIPS measures sets, the operational complexity of connecting APM performance to valid MIPS quality performance category scores in the necessary timeframe, as well as the uncertainty of the validity and equity of scoring results could unintentionally undermine the quality performance assessments in MIPS APMs. Finally, for purposes of performing valid evaluations of MIPS APMs, we must reduce the number of confounding factors to the extent feasible, which, in this case, would include reporting and assessment on non-APM quality measures. Thus, we propose to waive certain requirements of section 1848(q) of the Act for the first MIPS performance year to avoid risking adverse operational or program evaluation consequences for MIPS APMs while we work toward incorporating MIPS APM quality measures into MIPS scoring for future MIPS performance periods without. Accordingly, under section 1115A(d)(1) of the Act, we propose to waive—for MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program or the Next Generation ACO Model—the requirement under section 1848(q)(5)(E)(i)(I) of the Act that specifies the scoring weight for the quality performance category. With the proposed reduction of the quality performance category weight to zero, we believe it would be unnecessary to establish an annual final list of quality measures as required under section 1848(q)(2)(D) of the Act, or to specify and use quality measures in determining the MIPS CPS for these MIPS eligible clinicians. Therefore, under section 1115A(d)(1) of the Act, we propose to waive—for MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program or the Next Generation ACO Model—the requirements under sections 1848(q)(2)(D), 1848(q)(2)(B)(i) and 1848(q)(2)(A)(i) of the Act to establish a final list of quality measures (using certain criteria and processes); and to specify and use, respectively, quality measures in calculating the MIPS CPS, for these MIPS eligible clinicians.

We anticipate that beginning in the second MIPS performance period, the APM quality measure data submitted during the MIPS performance period to us would be used to derive a MIPs quality performance score for APM Entities in all APMs that meet criteria for application of the APM scoring standard. We anticipate that it may be necessary to propose policies and waivers of different requirements of the statute—such as one for section 1848(q)(2)(D) of the Act, to enable the use of non-MIPS quality measures in the quality performance category score—through future rulemaking. We expect that by the second MIPS performance period we will have had sufficient time to resolve operational constraints related to use of separate quality measure systems and adjust quality measure data submission timelines. Therefore, beginning with the second MIPS performance period, we anticipate that through use of the waiver authority under section 1115A(d)(1) of the Act, the quality measure data for APM Entities for which the APM scoring standard applies would be used for calculation of a MIPS quality performance score in a manner specified in future rulemaking. We seek comment on this transitional approach to use APM quality measures for the MIPS quality performance category for purposes of the APM scoring standard under MIPS in future years.

(14) MIPS APMs Other Than the Shared Savings Program and Next Generation ACO—Resource Use Performance Category Scoring Under the APM Scoring Standard

For the first MIPS performance period, we propose that, for MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program or the Next Generation ACO, to reduce the weight of the resource use performance category to zero. We propose this approach because: (1) APM Entity groups are already subject to cost and utilization performance assessments under MIPS APMs; (2) MIPS APMs usually measure resource use in terms of total cost of care, which is a broader accountability standard inherently encompasses the purpose of the claims-based measures that have relatively narrow clinical scopes, and MIPS APMs that do not measure resource use in terms of total cost of care may depart entirely from MIPS measures; and (3) the beneficiary attribution methodologies differ for measuring resource use under APMs and MIPS, leading to an unpredictable degree of overlap (for eligible clinicians and for CMS) between the sets of beneficiaries for which eligible clinicians would be responsible that would vary based on unique APM Entity characteristics such as which and how many eligible clinicians comprise an APM Entity. We believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population, the population identified through an APM must take priority to ensure that the goals and model evaluation associated with the APM are as clear and free of confounding factors as possible. The potential for different, conflicting results across APM and MIPS assessments creates uncertainty for MIPs eligible clinicians who are attempting to strategically transform their respective practices and succeed under the terms of an APM. Accordingly, under section 1115A(d)(1) of the Act, we propose to waive—for MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program or the Next Generation ACO Model—the requirement under section 1848(q)(5)(E)(i)(II) of the Act that specifies the scoring weight for the resource use performance category.

With the proposed reduction of the resource use performance category weight to zero, we believe it would be unnecessary to specify and use resource use measures in determining the MIPS CPS for these MIPS eligible clinicians. Therefore, under section 1115A(d)(1) of the Act, we propose to waive—for MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program or the Next Generation ACO Model—the requirements under section under sections 1848(q)(2)(B)(ii) and 1848(q)(2)(A)(ii) of the Act to specify and use, respectively, resource use measures in calculating the MIPS CPS for such eligible clinicians.

Given the proposal to waive requirements of section 1848(q) of the Act to reduce the weight of the quality and resource use performance categories to zero, we must subsequently specify how those weights would be redistributed among the remaining CPIA and advancing care information categories in order to maintain a total weight of 100 percent. We propose to redistribute the quality and the resource use performance category weights as specified in Table 14.

We understand that as the resource use performance category evolves, the rationale we discussed earlier for establishing a weight of zero for this performance category might not be applicable in future years. We seek comment on whether and how we should incorporate the resource use performance category into the APM scoring standard under MIPS. We also understand that reducing the quality and resource use performance category weight to zero and redistributing the weight to the CPIA and advancing care information performance categories could, to the extent that CPIA and advancing care information scores are higher than the scores MIPS eligible clinicians would have received under resource use, result in higher average scores for MIPs eligible clinicians in

APM Entity groups participating in MIPS APMs. We seek comment on the possible alternative of assigning a neutral score to MIPS eligible clinicians in APM Entity groups participating in MIPS APMs for the quality and resource use performance category in order to moderate APM Entity scores.

(15) MIPS APMs Other Than the Shared Savings Program and Next Generation ACO Model—CPIA and Advancing Care Information Performance Category Scoring Under the APM Scoring Standard

We propose that all MIPS eligible clinicians participating in a MIPS APM other than the Shared Savings Program or the Next Generation ACO would submit data for the CPIA and Advancing Care Information performance categories. We propose that these MIPS eligible clinicians would submit data for both the CPIA and advancing care information performance categories as individual MIPS eligible clinicians. MIPS eligible clinicians in these other APMs may belong to a billing TIN that includes MIPs eligible clinicians that do not participate in the APM. Therefore for both CPIA and the advancing care information performance category, we propose that these MIPS eligible clinicians submit individual level data to MIPS and not group level data.

For both the CPIA and advancing care information performance categories, the scores from all of the individual MIPS eligible clinicians in the APM Entity group would be aggregated to the APM Entity level and averaged for a mean score. Any individual MIPS eligible clinicians that do not submit data for the CPIA or advancing care information performance category would contribute a score of zero for that performance category in the calculation of the APM Entity score. All MIPS eligible clinicians in the APM Entity group would receive the same APM Entity group score.

Section 1848(q)(5)(C)(i) of the Act requires that MIPS eligible clinicians who are in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, with respect to a performance period shall be given the highest potential score for the CPIA performance category. Accordingly, a MIPS eligible clinician in an APM Entity group that meets the definition of a patient-centered medical home or comparable specialty practice, as discussed in section II.E.5.f. of this proposed rule, will receive the highest potential score. Additionally, section 1848(q)(5)(C)(ii) of the Act requires that MIPS eligible clinicians participating in APMs that are not patient-centered medical homes for a performance period shall earn a minimum score of one-half of the highest potential score for CPIA. We acknowledge that using this increased weight for CPIA may make it easier in the first performance period to attain a higher MIPS score. We do not have historical data to assess the range of scores under CPIA because this is the first time such activities are being assessed in such a manner.

With respect to the advancing care information performance category, we believe that MIPS eligible clinicians participating in MIPS APMs would be using certified health IT and other health information technology to coordinate care and deliver better care to their patients. Most MIPS APMs encourage participants to use health IT to perform population management, monitor their own quality improvement activities and, better coordinate care for their patients in a way that aligns with the goals of the advancing care information performance category. We want to ensure that where we propose reductions in weights for other MIPS performance categories, such weights are appropriately redistributed to the advancing care information performance category.

Therefore, for the first MIPS performance period, we propose that the weights for the CPIA and advancing care information performance categories would be 25 percent and 75 percent, respectively. We seek comment on our proposals for reporting and scoring the CPIA and advancing care information performance categories under the APM scoring standard. In particular, we seek comment on the appropriate weight distributions in the first year and subsequent years when we anticipate incorporating assessment in the quality performance category for all MIPS eligible clinicians participating in MIPS APMs.

Table 14 shows the performance category scoring and weights for other APMs for which the APM scoring standard applies.

TABLE 14: APMs other than the Shared Savings Program and Next Generation ACO Model – 2017 Performance Period for the 2019 Payment Adjustment

MIPS Performance Category	Alternative Payment Entity Data Submission Requirement	Performance Score	Performance Category Weight
Quality	The APM Entity group would not be assessed on quality under MIPS in the first performance period. The APM Entity group would submit quality measures to CMS required by the APM.	N/A	0%
Resource Use	The APM Entity group would not be assessed on resource use under MIPS in the first performance period.	N/A	0%
Clinical Improvement Performance Activities	All MIPs eligible clinicians in the APM Entity group would submit individual level data for this performance category	All MIPS eligible clinicians in the APM Entity group would receive a minimum of one half of the maximum score. Additionally, any MIPS eligible clinician in the APM Entity group participating in a patient-centered medical home or comparable specialty practice would receive the highest potential score. All APM Entity group eligible clinician scores will be aggregated and averaged to yield one APM Entity score. Any MIPS eligible clinician in the APM Entity group who does not submit data for this category would contribute a score of zero.	25%
Advancing Care Information	All MIPS eligible clinicians in the APM Entity group would submit individual level data for this performance category.	All APM Entity group eligible clinician scores would be aggregated and averaged to yield one APM Entity score. Any MIPs eligible clinician in the APM Entity group who does not submit data for this category would contribute a score of zero.	75%

(14) APM Entity Data Submission Method

Presently, CMS requires MIPS APMs to either use the CMS Web Interface or another data submission mechanism for submitting data on the quality measures for purposes of the APM. We are not currently proposing to change the method used by APM Entities to submit their data on quality measures to CMS for purposes of MIPS. Therefore, we expect that APM Entities like the Shared Savings Program ACOs would continue to submit their data on quality measures using the CMS Web Interface data submission mechanism. Similarly, participants in the Comprehensive ESRD Care (CEC) Initiative would continue to submit their quality measures to CMS using the Quality Measures Assessment Tool (QMAT) for purposes of the CEC quality performance assessment under the APM. All eligible clinicians in APM Entities participating in MIPS APMs would be required to use one of the proposed MIPS data submission mechanisms to submit data for the CPIA and advancing care information performance categories.

TABLE 15: APM Entity Submission Method for Each MIPS Performance Category

MIPS Performance Category	APM Entity Eligible Clinician Submission Method
Quality	The APM Entity group submits quality measure data to CMS as required under the APM
Resource Use	No data submitted by APM Entity group to MIPS.
CPIA	APM Entity group eligible clinicians submit data for this category using a MIPS data submission mechanism.
Advancing Care Information	APM Entity group eligible clinicians submit data for this category using a MIPS data submission mechanism.

(15) MIPS APM Performance Feedback

For the first MIPS performance feedback specified under section 1848(q)(12) of the Act to be published by July 1, 2017, we propose that all MIPS eligible clinicians participating in MIPS APMs would receive the same historical information prepared for all MIPS eligible clinicians except the report would indicate that the historical information provided to such MIPS eligible clinicians is for informational purposes only. MIPS eligible clinicians participating in APMs have been evaluated for performance only under the APM. Thus, historical information may not be representative of the scores that these MIPS eligible clinicians would receive under MIPS.

For MIPS eligible clinicians participating in MIPS APMs, we propose that the MIPS performance feedback would consist only of the scores applicable to the APM Entity group for the specific MIPS performance period. For example, the MIPS eligible clinicians participating in the Shared Savings Program and Next Generation ACO Model would receive performance feedback for the quality, CPIA, and advancing care information performance categories for the 2017 performance period. Because these MIPS eligible clinicians would not be assessed for the resource use performance category, information on MIPS performance scores for the resource use performance category would not be applicable to these MIPS eligible clinicians.

We also propose that, for the Shared Savings Program the performance feedback would be available to the eligible clinicians participating in the Shared Savings Program at the group billing TIN level. For the Next Generation ACO Model we propose that the performance feedback would be available to all MIPS eligible clinicians participating in the MIPS APM Entity.

We propose that in the first MIPS performance period, the MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program or the Next Generation ACO Model would receive performance feedback for the CPIA and advancing care information only, as they would not be assessed under the quality or resource use performance categories. The information such as MIPS measure score comparisons for the quality and resource use performance categories would not be applicable to these MIPS eligible clinicians because no such comparative data would exist. We propose the performance feedback for all other MIPS eligible clinicians participating in APMs would be available for each MIPS eligible clinician that submitted MIPS data for these performance categories under their respective APM Entities. We invite comment on these proposals.

6. MIPS Composite Performance Score Methodology

By incentivizing quality and value for all eligible clinicians, MIPS creates a new mechanism for calculating eligible clinician payments. To implement this vision, we propose a scoring methodology that allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. Further, we propose a scoring methodology that is meaningful, understandable and flexible for all MIPS eligible clinicians. Our proposed methodology allows for multiple pathways to success with flexibility for the variety of practice types and reporting options. First, we have proposed multiple ways that MIPS eligible clinicians may submit data to MIPS for the quality performance category. Second, we generally do not propose "all-or-nothing" reporting requirements for MIPS. Third, bonus points would be available for reporting high priority measures and electronic reporting of quality data. Recognizing that MIPS is a new program, we also outline proposals which we believe are operationally feasible for us to implement in the first year, while maintaining our longer-term vision, as well as Congress' vision.

Section 1848(q) of the Act requires the Secretary to: (1) Develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for a performance period for a year; (2) using the methodology, provide a composite performance score for each MIPS eligible clinician for each performance period; and (3) use the CPS of the MIPS eligible clinician for a performance period to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the MIPS eligible clinician for the MIPS payment year. Section II.E.5 of this rule proposes the measures and activities for each of the four MIPS performance categories: Quality, resource use, CPIA, and advancing care information. This section proposes the performance standards for the measures and activities for each of the four performance categories under section 1848(q)(3) of the Act, the methodology for determining a score for each of the four performance categories (referred to as a "performance category score"), and the methodology for determining a CPS under section 1848(q)(5) of the Act based on the scores determined for each of the four performance categories. The performance category score is defined at § 414.1305 as the assessment of each MIPS eligible clinician's performance on the applicable measures and activities for a performance category for a performance period based on the performance standards for those measures and activities. Section II.E.7. includes proposals for determining the MIPS adjustments factors based on the CPS.

As noted in section II.E.2., we propose to use multiple identifiers to allow MIPS eligible clinicians to be measured as individuals, or collectively as part of a group or an APM Entity group (an

APM Entity participating in a MIPS APM). Further, in section II.E.5.a.2., we propose that data for all four MIPS performance categories would be submitted using the same identifier (either individual or group) and that the CPS would be calculated using the same identifier. The scoring proposals in this section II.E.6. would be applied in the same manner for either individual submissions, proposed as TIN/NPI, or for the group submissions using the TIN identifier. Unless otherwise noted, for purposes of this section, the term "MIPS eligible clinician" will refer to both individual and group reporting and scoring, but will not refer to an APM Entity group.

APM Entity group reporting and scoring for MIPS eligible clinicians participating in MIPS APMs are described in section II.E.5.h. of this proposed rule. All eligible clinicians that participate in APMs are considered MIPS eligible clinicians unless and until they are determined to be either QPs or Partial QPs who elect not to report under MIPS, and excluded from MIPS. For the APM scoring standard to apply to a MIPS eligible clinician, the eligible clinician must be listed as a participant in the APM Entity that participates in a MIPS APM as of December 31 of the performance period, as described in section II.E.5.h. CMS will publish a list of MIPS APMs on the CMS Web site in advance of the performance period.

MIPS eligible clinicians who participate in APMs that are not MIPS APMs would report to MIPS as an individual MIPS eligible clinician or group. Unless otherwise specified, the proposals in this section II.E.6 that relate to reporting and scoring of measures and activities do not affect the APM scoring standard.

Our rationale for our scoring methodology is grounded in the understanding that the MIPS scoring system is a complex system with numerous moving parts. Thus, we believe it is necessary to set up key parameters around scoring, including requiring MIPS eligible clinicians to report at the individual or group level across all performance categories and generally to submit information for a performance category using a single submission mechanism. Too many different permutations would create additional complexities that could create confusion amongst MIPS eligible clinicians as to what is and is not allowed.

a. Converting Measures and Activities Into Performance Category Scores

(1) Policies That Apply Across Multiple Performance Categories

The detailed policies for scoring the four performance categories are described in this section II.E.6.a. of this rule. However, as the four performance categories collectively create a single MIPS CPS, there are some cross-cutting policies that we propose to apply to multiple performance categories.

(a) Performance Standards

Section 1848(q)(3)(A) of the Act requires the Secretary to establish performance standards for the measures and activities in the four MIPS performance categories. Section 1848(q)(3)(B) of the Act requires the Secretary, in establishing performance standards for measures and activities for the four MIPS performance categories, to consider historical performance standards, improvement, and the opportunity for continued improvement. We propose to define the term, performance standards, at § 414.1305 as the level of performance and methodology that the MIPS eligible clinician is assessed on for a MIPS performance period at the measures and activities level for all MIPS performance categories. We define the term, MIPS payment year at § 414.1305 as the calendar year in which MIPS payment adjustments are be applied. Performance standards for each performance category are proposed in more detail later in this section, II.E.6. MIPS eligible clinicians would know the actual performance standards in advance of the performance period, when possible. Further, each performance category is unified under the principle that MIPS eligible clinicians would know, in advance of the performance period, the methodology for determining the performance standards and the methodology that would be used to score their performance. Table 16 summarizes the performance standards, which are proposed in more detail in section II.E.6.a.

TABLE 16: Performance Category Performance Standards

Performance Category	Performance Standard
Quality	Measure benchmarks to assign points, plus bonus points.
Resource Use	Measure benchmarks to assign points.
CPIA	Based on participation in activities that align with the patient-centered medical home. The number of points from reported activities compared against a static highest potential score of 60 points.
Advancing Care Information	Based on participation (base score) and performance (performance score). Base score: Achieved by meeting the Protect Patient Health Information objective and reporting the numerator (of at least one) and denominator or yes/no statement as applicable (only a yes statement would qualify for credit under the base score) for each required measure. Performance score: decile scale for additional achievement on measures above the base score requirements.

(b) Unified Scoring System

Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for applicable measures and activities in each performance category applicable to the MIPS eligible clinician for a performance period. While MIPS has four different performance categories, we propose a unified scoring system that enables MIPS eligible clinicians, beneficiaries, and stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements. We sought to keep the scoring as simple as possible, while providing flexibility for the variety of practice types and reporting options. We would incorporate the following characteristics into the proposed scoring methodologies for each of the four MIPS performance categories:

- For the quality and resource use performance categories, all measures would be converted to a 10-point scoring system which provides a framework to universally compare different types of measures across different types of MIPS eligible clinicians. A similar point framework has been successfully implemented in several other CMS quality programs including the Hospital Value-Based Purchasing Program (HVBP).
- The measure and activity performance standards would be published, where feasible, before the performance period begins, so that MIPS eligible clinicians can track their performance during the performance period. This transparency would make the information more actionable to MIPS eligible clinicians.
- Unlike the PQRS or the EHR Incentive Program, we generally would not include "all-or-nothing" reporting requirements for MIPS. The methodology would score measures and activities that meet certain standards defined in section II.E.5 and this section. However, section 1848(q)(5)(B)(i) of the Act provides that under the MIPS scoring methodology, MIPS eligible clinicians who fail to report on an applicable measure or activity that is required to be reported shall be treated as receiving the lowest possible score for the measure or activity. Therefore, MIPS eligible clinicians that fail to report specific measures or activities would receive zero points for each required measure or activity that they do not submit to MIPS.
- The scoring system would ensure sufficient reliability and validity, by only scoring the measures that meet certain standards (such as required case minimum). The standards are described later in this section.
- The scoring proposals provide incentives for MIPS eligible clinicians to invest and focus on certain measures and activities that meet high priority policy goals such as improving beneficiary health, improving care coordination through health information exchange, or encouraging APM Entity participation.
- Performance at any level would receive points towards the performance category scores.

For the first year of MIPS, there are some minor differences in the proposed performance category scoring methodologies to account for differences in the maturity of the data collection systems and the measures and activities; however, we anticipate that the scoring in future years would continue to align and simplify. We request comment on the characteristics of the proposed unified scoring system.

We also propose at § 414.1325 that MIPS eligible clinicians and groups may elect to submit information via multiple mechanisms; however, they must use the same identifier for all performance categories and they may only use one submission mechanism per performance category. For example, a MIPS eligible clinician could use one submission mechanism for sending quality measures and another for sending CPIA data, but a MIPS eligible clinician could not use two submission mechanisms for a single performance category, such as submitting three quality measures via claims and three quality measures via registry. We do intend to allow flexibility, for example, in rare situations where a MIPS eligible clinician submits data for a performance category via multiple submission mechanisms (for example, submits data for the quality performance category through a registry and QCDR), we would score all the options and use the highest performance category score for the eligible clinician.

In carrying out MIPS, section 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs under section 1848(m)(3)(E) of the Act. In addition, section 1848(q)(5)(B)(ii) of the Act provides that under the methodology for assessing the total performance of each MIPS eligible clinician, the Secretary shall encourage MIPS eligible clinicians to report on applicable measures under the quality performance category through the use of CEHRT and QCDRs. To encourage the use of QCDRs, we have created opportunities for QCDRs to report new and innovative quality measures. In addition, several CPIAs emphasize QCDR participation. Finally, we propose under section II.E.5.a. for QCDRs to be able to submit data on all MIPS performance categories. We believe these flexible options would allow MIPS eligible clinicians to meet the submission criteria for MIPS in a low burden manner, which in turn may positively affect their CPS.

In addition, section 1848(q)(5)(D) of the Act lays out the requirements for incorporating performance improvement into the MIPS scoring methodology beginning with the second MIPS performance period, if data sufficient to measure improvement is available. Section 1848(q)(5)(D)(ii) of the Act also provides that achievement may be weighted higher than improvement. Stated generally, we consider achievement to mean how a MIPS eligible clinician performs compared to other MIPS eligible clinicians for each applicable measure and activity in a performance category, and improvement to mean how a MIPS eligible clinician performs compared to the MIPS eligible clinician's own previous performance on measures and activities in a performance category. Improvement would not be scored for the first year of MIPS, but we seek comment on how best to incorporate improvement scoring for all performance categories.

(c) Baseline Period

In other Medicare quality programs, such as the HVBP, we have adopted a baseline period that occurs prior to the performance period for a program year to measure improvement and to establish performance standards. We view the MIPS Program as necessitating a similar baseline period for the quality performance category. We intend to establish a baseline period for each performance period for a MIPS payment year to measure improvement for the quality performance category and to enable us to calculate performance standards that we can establish and announce prior to the performance period. As with the HVBP, we intend to adopt baseline periods that are as close as possible in duration to the performance period specified for a MIPS payment year. In addition, evaluating performance compared to a baseline period may enable other payers to incorporate MIPS benchmarks into their programs. For each MIPS payment year, we propose at § 414.1380 that the baseline period would be two years prior to the performance period for the MIPS payment year. Therefore, for the first MIPS payment year (CY 2019 payment adjustments), for the quality performance category, we propose that the baseline period would be calendar year 2015 which is 2 years prior to the proposed calendar year 2017 performance period. As discussed in section II.E.6.a.2.a. we propose to use performance in the baseline period to set benchmarks for the quality performance category, with the exception of new measures for which we would set the benchmarks using performance in the performance period. For the resource use performance category, we propose to set the benchmarks using performance in the performance period and not the baseline period, as discussed in section II.E.6.a.3. For the resource use performance category, we also have included an alternative proposal to set the benchmarks using performance in the baseline period. We define the term "measure benchmark" for the quality and resource use performance categories at § 414.1305 as the level of performance that the MIPS eligible clinician will be assessed on for a performance period at the measures level.

(2) Scoring the Quality Performance Category

In section II.E.5.b.3, we proposed multiple ways that MIPS eligible clinicians may submit data for the quality performance category to MIPS; however, we propose that the scoring methodology would be consistent regardless of how the data is submitted. In summary, we propose at § 414.1380(b)(1) to assign 1–10 points to each measure based on how a MIPS eligible clinician's performance compares to benchmarks. Measures must have the required case minimum to be scored. If a MIPS eligible clinician fails to submit a measure required under the quality performance category criteria, then the MIPS eligible clinician would receive zero points for that measure. MIPS eligible clinicians would not receive zero points if the required measure is submitted (meeting the data completeness criteria as defined in section II.E.5.b.3.b.) but is unable to be scored for any of the reasons listed in this section II.E.6.a.2., such as not meeting the required case minimum or a measure lacks a benchmark). For example, if a MIPS eligible clinician reports a measure that meets the requirements specified in section II.E.5.b., but that measure does not meet the required case minimum criteria or lacks a benchmark, then the measure would not be scored under the MIPS quality performance category, whereas a MIPS eligible clinician that did not report this measure would have the measure scored as a zero. We describe in section II.E.6a.2.d. examples of how points would be allocated and how to compute the overall quality performance category score under these scenarios. Bonus points would be available for reporting high priority measures, defined as outcome, appropriate use, efficiency, care coordination, patient safety, and patient experience measures.

As discussed in section II.E.6.a.2.g., the quality performance category score would be the sum of all the points assigned for the scored measures required for the quality performance category plus the bonus points (subject to the cap) divided by the sum of total possible points. Since MIPS eligible clinicians would be generally required to submit six measures or six measures from a specialty measure set and we would also score MIPS eligible clinicians on up to three population-based measures calculated from administrative claims data as discussed in section II.5.b.6, the total possible points for the quality performance category would be 90 points (6 submitted measures × 10 points + 3 population-based measures × 10 points = 90). However, for eligible groups reporting via CMS Web Interface, the total possible points for the quality performance category would be 210 points (17 measures × 10 points + 3 population-based measures × 10 points = 200), subject to CMS Web Interface reporting criteria. Further, the total possible points for small groups of less than 10 would be 80 points (6 submitted measures × 10 points + 2 population-based measures × 10 points = 80) because under our proposals the all-cause hospital readmissions measure would not be applicable to groups of less than 10 MIPS eligible clinicians and MIPS eligible clinicians reporting as individuals due to reliability concerns. Therefore, small groups of less than 10 and MIPS eligible clinicians reporting as individuals would only be scored on two population-based measures.

In section II.E.6.b, we discuss how we would score MIPS eligible clinicians who do not have any scored measures in the quality performance category. The details of the proposed scoring methodology for the quality performance category are described below.

(a) Quality Measure Benchmarks

For the quality performance category, we propose at § 414.1380(b)(1) that the performance standard is measure-specific benchmarks. Benchmarks would be determined based on performance on measures in the baseline period. For quality performance category measures for which there are baseline period data, we would calculate an array of measure benchmarks based on performance during the baseline period, breaking baseline period measure performance into deciles. Then, a MIPS eligible clinician's actual measure performance during the performance period would be evaluated to determine the number of points that should be assigned based on where the actual measure performance falls within these baseline period benchmarks. If a measure does not have baseline period information, (for example, new measures) or if the measure specifications for the baseline period differ substantially from the performance period (for example, when the measure requirements change due to updated clinical guidelines), then we would determine the array of benchmarks based on performance on the measure in the performance period, breaking the actual performance on the measure into deciles. In addition, we propose to create separate benchmarks for submission mechanisms that do not have comparable measure specifications. For example, several electronic clinical quality measures have specifications that are different than the corresponding measure from registries. We propose to develop separate benchmarks for EHR submission options, claims submission options, Qualified Clinical Data Registries (QCDRs) and qualified registries submission options.

For CMS Web Interface reporting, we propose to use the benchmarks from the Shared Savings Program as described at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality-Measures-Standards.html.* We would adopt the Shared Savings Program performance year benchmarks for measures that are reported through the CMS Web Interface for the MIPS performance period, but would apply the MIPS method of assigning 1 to 10 points to each measure. For example, for the 2017 MIPS performance year, we would use the benchmarks for the 2017 Shared Savings Program performance year, as both the MIPS performance period and the Shared Savings Program performance year use a calendar year for CMS Web Interface reporting. Because the Shared Savings Program does not create benchmarks below the 30th percentile, we would assign all scores below the 30th percentile a value of 2 points, which is consistent with the mid-cluster approach we are proposing for topped out measures. We believe using the same benchmarks for MIPS and the Shared Savings Program for the CMS Web Interface measures would be appropriate because, as is discussed in II.E.5.h., we propose to use the MIPS benchmarks to score the Shared Savings Program and the Next Generation ACO Model on the quality performance category and believe it is important to not have conflicting benchmarks. We would post the MIPS CMS Web Interface benchmarks with the other MIPS benchmarks.

As an alternative approach, we considered creating CMS Web Interface specific benchmarks for MIPS. This alternative would be restricted to CMS Web Interface reporters and would not include other MIPS data submission methods, which are currently used to create the Shared Saving Program benchmarks. This alternative would also apply the topped out cluster approach if any measures are topped out. While we see benefit in having CMS Web Interface methodology match the other MIPS benchmarks, we are also concerned about the Shared Saving Program and the Next Generation ACO Model participants having conflicting benchmark data. We request comments on building CMS Web Interface specific benchmarks.

All MIPS eligible clinicians, regardless of whether they report as an individual or group, and regardless of specialty, that submit data using the same submission mechanism would be included in the same benchmark. We propose to unify the calculation of the benchmark by using the same approach as the VM of weighting the performance rate of each MIPS eligible clinician and group submitting data on the quality measure by the number of beneficiaries used to calculate the performance rate so that group performance is weighted appropriately (77 FR 69321–69322). We would also include APM Entity submissions in the benchmark but would not score APM Entities using this methodology. For APM scoring, we refer to section II.E.5.h.

To ensure that we have robust benchmarks, we propose that each benchmark must have a minimum of 20 MIPS eligible clinicians who reported the measure meeting the data completeness requirement defined in section II.E.5.b.3, as well as meeting the required case minimum criteria for scoring that is defined later in this section. We selected a minimum of 20 because, as discussed below, our benchmarking methodology relies on assigning points based on decile distributions with decimals. A decile distribution requires at least 10 observations. We doubled the requirement to 20 so that we would be able to assign decimal point values and minimize cliffs between deciles. We did not want to increase the benchmark sample size requirement due to concerns that an increase could limit the number of measures with benchmarks.

We also propose that MIPS eligible clinicians who report measures with a performance rate of 0 percent would not be included in the benchmarks. In our initial analysis, we identified some measures that had a large cluster of eligible clinicians with a 0 percent performance rate. We are concerned that the 0 percent performance rate represents clinicians who are not actively engaging in that measurement activity. For example, it could be clinicians reporting the measures that are programmed into their EHR and that are submitted unintentionally, rather than measures the eligible clinician has actively selected for quality improvement. We do not want to inappropriately skew the distribution. We seek comment on whether or not to include 0 percent performance in the benchmark.

We propose at § 414.1380(b)(1)(i) to base the benchmarks on performance in the baseline period when possible, and to publish the numerical benchmarks when possible, prior to the start of the performance period. In those cases where we do not have comparable data from the baseline period, we propose to use information from the performance period to establish benchmarks. While the benchmark methodology would be established in a final rule in advance of the performance period, the actual numerical benchmarks would not be published until after the performance period for quality measures that do not have comparable data from the baseline period. The methodology for creating the benchmarks is discussed below in this section.

We considered not scoring measures that either are new to the MIPS program or do not have a historical benchmark based on performance in the baseline period. This policy would be consistent with the VM policy in which we do not score measures that have no benchmark (77 FR 69322). However, we are concerned that such a policy could stifle reporting on innovative new measures because it would take several years for the measure to be incorporated into the performance category score. We also believe that any issues related to reporting a new measure would not disproportionately affect the relative performance between MIPS eligible clinicians.

We also considered a variation on the scoring methodology that would provide a floor for a new MIPS measure. Under this variation, if a MIPS eligible clinician reports a new measure under the quality performance category, the MIPS eligible clinician would not score lower than 3 points for that measure. This would encourage reporting on new measures, but also prevent MIPS eligible clinicians from receiving the lowest scores for a new measure, while still measuring variable performance. Finally, we also considered lowering the weight of a new measure, so that new measures would contribute relatively less to the score compared to other measures. In the end, we are not proposing these alternatives we considered, because we want to encourage adoption and measured performance of new measures, however, we do request comment on these alternatives, including comments on what the lowest score should be for MIPS eligible clinicians who report a new measure under the quality performance category and protections against potential gaming related to reporting of new measures only. We also seek comments on alternative methodologies for scoring new measures under the quality performance category, which would assure equity in scoring between the methodology for measures for which there is baseline period data and for new measures which do not have baseline period data available.

Finally, we want to clarify that some PQRS reporting mechanisms have limited experience with all-payer data. For example, under PQRS, all-payer data was permitted only when reporting via registries for measure groups; reporting via registries for individual measures was restricted to Medicare only. Under MIPS however, we intend to have more robust data submissions, as described in section II.E.5.b.3. We recognize that comparing all-payer performance to a benchmark that is built, in part, on Medicare data is a limitation and would monitor the benchmarks to see if we need to develop separate benchmarks. This data issue would resolve in a year or two, as new MIPS data becomes the historical benchmark data in future years.

(b) Assigning Points Based on Achievement

We propose at § 414.1380(b)(1)(x) to establish benchmarks using a percentile distribution, separated by decile categories, because it translates measure-specific score distributions into a uniform distribution of MIPS eligible clinicians based on actual performance values. For each set of benchmarks, we propose to calculate the decile breaks for measure performance and assign points for a measure based on which benchmark decile range the MIPS eligible clinician's performance rate on the measure falls between. For example, MIPS eligible clinicians in the top decile would receive 10 points for the measure, and MIPS eligible clinicians in the next lower decile would receive points ranging from 9 to 9.9. We propose to assign partial points to prevent performance cliffs for MIPS eligible clinicians near the decile breaks. The partial points would be assigned based on the percentile distribution.

Table 17 illustrates an example of using decile points along with partial points to assign achievement points for a sample quality measure. The methodology in this example could apply to measures where the benchmark is based on the baseline period or for new measures where the benchmark is based on the performance period.

TABLE 17: Example of Using Benchmarks for a Single Measure to Assign Points

Decile	Sample Quality Measure Benchmarks	Possible Points
Benchmark Decile 1	0-6.9%	1.0-1.9
Benchmark Decile 2	7.0-15.9%	2.0-2.9
Benchmark Decile 3	16.0-22.9%	3.0-3.9
Benchmark Decile 4	23.0-35.9%	4.0-4.9
Benchmark Decile 5	36.0-40.9%	5.0-5.9
Benchmark Decile 6	41.0-61.9%	6.0-6.9
Benchmark Decile 7	62.0-68.9%	7.0-7.9
Benchmark Decile 8	69.0-78.9%	8.0-8.9
Benchmark Decile 9	79.0-84.9%	9.0-9.9
Benchmark Decile 10	85.0%-100%	10

In the example above, a MIPS eligible clinician with a measure performance rate of 41 percent would receive 6.0 points based on the benchmark. MIPS eligible clinicians with measure performance rates of 85 percent or above would receive 10 points because they were in the top benchmark decile. We believe that MIPS eligible clinicians within the top decile in performance would warrant receiving the maximum number of points. This is a similar concept to the HVBP "benchmark" level. We note that 85 percent is solely illustrative. Any MIPS eligible clinician who reports some level of performance would receive a minimum of one point for reporting if the measure has the required case minimum, assuming the measure has a benchmark.

In Table 17 we described our scoring approach, using deciles. We do not propose to base scoring on decile distributions for the same measure ranges as described in Table 17 when performance is clustered at the high end (that is, "topped out" measures), as true variance cannot be assessed. MIPS eligible clinicians report on different measures and often elect to submit measures on which they expect to perform well. With MIPS eligible clinicians electing to report on measures where they expect to perform well, we anticipate many measures would have performance distributions clustered near the top. We propose to identify "topped out" measures by using a definition similar to the definition used in the HVBP: Truncated Coefficient of Variation [13] is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors; [14] or median value for a process measure that is 95 percent or greater (80 FR 49550).[15]

Using 2014 PQRS quality reported data measures, we modeled the proposed benchmark methodology and identified that approximately half of the measures proposed under the quality performance category are topped out. Several measures have a median score of 100 percent, which makes it difficult to assess relative performance needed for the quality performance category score.

However, we do not believe it would be appropriate to remove topped out measures at this time. As not all MIPS eligible clinicians would be required to report these measures under our proposals for the quality performance category in section II.E.5.b. it would be difficult to determine whether a measure is truly topped out or if only excellent performers are choosing to report the measure. We also believe removing such a large volume of measures would make it difficult for some specialties to have enough applicable measures to report. At the same time, we do not believe that the highest values on topped out measures convey the same meaning of relative quality performance as the highest values for measures that are not topped out. In other words, we do not believe that eligible clinicians electing to report topped out process measures should be able to receive the same maximum score as eligible clinicians electing to report preferred measures, such as outcome measures.

Therefore, we propose to modify the benchmark methodology for topped out measures. Rather than assigning up to 10 points per measure, we propose to limit the maximum number of points a topped out measure can achieve based on how clustered the scores are. We propose to identify clusters within topped out measures and would assign all MIPS eligible clinicians within the cluster the same value, which would be the number of points available at the midpoint of the cluster. That is, we would take the midpoint of the highest and lowest scores that would pertain if the measure was not topped out and the values were not clustered. We would only apply this methodology for benchmarks based on the baseline period. When we develop the benchmarks, we would identify the clusters and state the points that would be assigned when the measure performance rate is in a cluster. We would notify MIPS eligible clinicians when those benchmarks are published with regard to which measures are topped out.

Table 18 illustrates this hypothetical example. In developing the benchmark, we identified that the top five deciles (50 percent of eligible clinicians reporting the measure) of MIPS eligible clinicians are clustered at 100 percent. We would identify the middle of that cluster (in this example, the top 25 percent or the middle of the eighth decile) and then assign all MIPS eligible clinicians with performance rates in the cluster the same number of points for the measure. The decile points for the hypothetical topped out measure in Table 18 shows that the maximum a MIPS eligible clinician can receive for the topped out measure is 8.5 points in this example.

TABLE 18: Example of Using Benchmarks for Topped Out Measures

Decile	Sample Quality Measure Benchmarks	Possible Points
Benchmark Decile 1	0%-74.9%	1.0-1.9
Benchmark Decile 2	75%-79.9%	2.0-2.9
Benchmark Decile 3	80%-84.9%	3.0-3.9
Benchmark Decile 4	85%-94.9%	4.0-4.9
Benchmark Decile 5	95%-99.9%	5.0-5.9
Benchmark Deciles 6-10	100%	Midpoint value = 8.5 points

We propose this approach because we want to encourage MIPS eligible clinicians not to report topped out measures, but to instead choose other measures that are more meaningful. We also seek feedback on alternative ways and an alternative scoring methodology to address topped out measures so that topped out measures do not disproportionately affect a MIPS eligible clinician's quality performance category score. Other alternatives could include placing a limit on the number of topped out measures MIPS eligible clinicians may submit or reducing the weight of topped out measures. We also considered whether we should apply a flat percentage in building the benchmarks, similar to the Shared Savings Program, where MIPS eligible clinicians are scored on their percentage of their performance rate and not on a decile distribution and request comment on how to apply such a methodology without providing an incentive to report topped out measures. Under the Shared Savings Program, 42 CFR 425.502, there are circumstances when benchmarks are set using flat percentages. For some measures, benchmarks are set using flat percentages when the 60th percentile was equal to or greater than 80.00 percent, effective beginning with the 2014 reporting year (78 FR 74759–74763). For other measures benchmarks are set using flat percentages when the 90th percentile was equal to or greater than 95.00 percent, effective beginning in 2015 (79 FR 67925). Flat percentages allow those with high scores to earn maximum or near maximum quality points while allowing room for improvement and rewarding that improvement in subsequent years. Use of flat percentages also helps ensure those with high performance on a measure are not penalized as low performers. We also note that we anticipate removing topped out measures over time, as we work to develop new quality measures that will eventually replace these topped out measures. We request feedback on these proposals.

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[13] The 5% of MIPS eligible clinicians with the highest scores, and the 5% with lowest scores are removed before calculating the Coefficient of Variation.

[14] This is a test of whether the range of scores in the upper quartile is statistically meaningful.

[15] This last criterion is in addition to the HVBP definition.

(c) Case Minimum Requirements and Measure Reliability and Validity

We seek to ensure that MIPS eligible clinicians are measured reliably; therefore, we propose at § 414.1380(b)(1)(v) to use for the quality performance category measures the case minimum requirements for the quality measures used in the 2018 VM (see § 414.1265): 20 cases for all quality measures, with the exception of the all-cause hospital readmissions measure, which has a minimum of 200 cases. We refer readers to Table 46 of the CY 2016 PFS final rule (80 FR 71282) which summarized our analysis of the reliability of certain claims-based measures used for the 2016 VM payment adjustment. MIPS eligible clinicians that report measures with fewer than 20 cases (and the measure meets the data completeness criteria) would receive recognition for submitting the measure, but the measure would not be included for MIPS quality performance category scoring. Since the all-cause hospital readmissions measure does not meet the threshold for what we consider to be moderate reliability for solo practitioners and groups of less than ten MIPS eligible clinicians for purposes of the VM (see Table 46 of the CY 2016 PFS final rule, referenced above), for consistency, we propose to not include the all-cause hospital readmissions measure in the calculation of the quality performance category for MIPS eligible clinicians who individually report, as well as solo practitioners or groups of two to nine MIPS eligible clinicians.

We also propose that if we identify issues or circumstances that would impact the reliability or validity of a measure score, we would also exclude those measures from scoring. For example, if we discover that there was an unforeseen data collection issue that would affect the integrity of the measure information, we would not want to include that measure in the quality performance category score. If a measure is excluded, we would recognize that the measure had been submitted and would not disadvantage the MIPS eligible clinicians by assigning them zero points for a non-reported measure. In this instance, if the MIPS eligible clinician, as a solo practitioner, scored 10 out of 10 on each of the remaining five measures submitted, and the two population-based measures applicable to solo practitioners, the MIPS eligible clinician would receive a perfect score in the quality performance category (5 measures × 10 points) + (2 population-based measures × 10 points) or 70 out of 70 possible points.

(d) Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria

Section II.E.5.b. of this proposed rule outlines our proposed quality performance category criteria for the different reporting mechanisms. The criteria vary by reporting mechanism, but generally we propose to include a minimum of six measures with at least one cross-cutting measure (for patient facing MIPS eligible clinicians) (Table C) and an outcome measure if available. If an outcome measure is not available, then the eligible clinician would report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. MIPS eligible clinicians and groups would have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.

We note that there are some special scenarios for those MIPS eligible clinicians who select their measures from the Specialty Sets (Table E) as discussed in section II.E.5.b.

For groups using the CMS Web Interface and MIPS APMs, we propose to have different quality performance category criteria described in sections II.E.5.b. and II.E.5.h. Additionally, as described in section II.E.5.b. we also propose to score MIPS eligible clinicians on up to three population-based measures.

Previously in PQRS, EPs had to meet all the criteria or be subject to a negative payment adjustment. We heard from numerous commenters a desire to move away from "all-or-nothing" scoring. Therefore, in MIPS, we propose that MIPS eligible clinicians receive credit for measures that they report, regardless of whether or not the MIPS eligible clinician meets the quality performance category submission criteria. Section 1848(q)(5)(B)(i) of the Act provides that under the MIPS scoring methodology, MIPS eligible clinicians who fail to report on an applicable measure or activity that is required to be reported shall be treated as receiving the lowest possible score for the measure or activity; therefore, for any MIPS eligible clinician who does not report a measure required to satisfy the quality performance category submission criteria, we propose that the MIPS eligible clinician would receive zero points for that measure. For example, a MIPS eligible clinician who is able to report on six measures, yet reports on four measures, would receive two "zero" scores for the missing measures. In another example, a patient facing MIPS eligible clinician reports more than six measures, but does not elect to report a cross-cutting measure and an outcome measure, or if one is not available, another high priority measure. The MIPS eligible clinician in that scenario would receive at least two "zero" scores for not reporting measures required by the quality performance category criteria.

However, MIPS eligible clinicians who report a measure that does not meet the required case minimum would not be scored on the measure but would also not receive a "zero" score. For example, a MIPS eligible clinician who submits six measures as part of a group with 10 or more clinicians, one of which does not meet the required case minimum, would be scored on the five remaining measures and the three population-based measures based on administrative claims data. If the MIPS eligible clinician scored 10 out of 10 on each of these measures, the MIPS eligible clinician would receive a perfect score in the quality performance category (5 measures × 10 points) + (3 population-based measures × 10 points) or 80 out of 80 possible points.

We also note that if MIPS eligible clinicians are able to submit measures that can be scored, we want to discourage them from continuing to submit the same measures year-after-year that cannot be scored due to not meeting the required case minimum. Rather, to the fullest extent possible, MIPS eligible clinicians should select measures that would have a required case minimum. We seek comment on any safeguards we should implement in future years to minimize any gaming attempts. For example, if the measures that a MIPS eligible clinician submits for a performance period are not able to be scored due to not meeting the required case minimum, we seek comment on whether we should require these MIPS eligible clinicians to submit different measures with sufficient cases for the next performance period (to the extent other measures are applicable and available to them).

MIPS eligible clinicians who report a measure where there is no benchmark due to less than 20 MIPS eligible clinicians reporting on the measure would not be scored on the measure but would also not receive a "zero" score. Instead, these MIPS eligible clinicians would be scored according to the following example: A MIPS eligible clinician who submits six measures through a group of 10 or more clinicians, with one measure lacking a benchmark, would be scored on the five remaining measures and the three population-based measures based on administrative claims data. If the MIPS eligible clinician scored 10 out of 10 on each of these measures, the MIPS eligible clinician would receive a perfect score in the quality performance category (5 measures × 10 points) + (3 population-based measures × 10 points) or 80 out of 80 possible points.

We intend to develop a validation process to review and validate a MIPS eligible clinician's inability to report on the quality performance requirements as proposed in section II.E.5.b. We anticipate that this process would function similar to the Measure Applicability Validity (MAV) process that occurred under PQRS, with a few exceptions. First, the MAV process under PQRS was a secondary process after an EP was determined to not be a satisfactory reporter. Under MIPS, we intend to build the process into our overall scoring approach to reduce confusion and burden on MIPS eligible clinicians by having a separate process. Second, as the requirements under PQRS are different than those proposed under MIPS, the process must be updated to account for different measures and different quality performance requirements. More information on the MAV process under PQRS can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016_PQRS_MAV_Process forClaimsBasedReporting_030416.pdf.* We request comments on these proposals.

(e) Incentives To Report High Priority Measures

Consistent with other CMS value-based payment programs, we propose that MIPS scoring policies would emphasize and focus on high priority measures that impact beneficiaries. These high priority measures are defined as outcome, appropriate use, patient safety, efficiency, patient experience and care coordination measures; see Tables A–D for these measures. We propose these measures as high priority measures given their critical importance to our goals of meaningful measurement and our measure development plan. We note that many of these measures are grounded in NQS domains. For patient safety, efficiency, patient experience and care coordination measures, we refer to the measures within the respective NQS domains and measure types. For outcomes measures, we include both outcomes measures and intermediate outcomes measures. For appropriate use measures, we have noted which measures fall within this category in Tables A–D and provided criteria for how we identified these measures in section II.E.5.b. For non-MIPS measures reported through QCDRs, we propose to classify which measures are high priority during the measure review process.

We are proposing scoring adjustments to create incentives for MIPS eligible clinicians to submit certain high priority measures and to allow these measures to have more impact on the total quality performance category score.

We propose to create an incentive for MIPS eligible clinicians to voluntarily report additional high priority measures. We propose to provide two bonus points for each outcome and patient experience measure and one bonus point for other high priority measures reported in addition to the one high priority measure (an outcome measure, but if one is not available, then another high priority measure) that would already be required under the proposed quality performance category criteria. For example, if a MIPS eligible clinician submitted two outcome measures, and two patient safety measures, the MIPS eligible clinician would receive two bonus points for the second outcome measure reported and two bonus points for the two patient safety measures. The MIPS eligible clinician would not receive any bonus points for the first outcome measure submitted since that is a required measure. We selected two bonus points for outcome measures given the statutory requirements under section 1848(q)(2)(C)(i) of the Act to emphasize outcome measures. We selected two bonus points for patient experience measures given the importance of patient experience measures to our measurement goals. We selected one bonus point for all other high priority measures given our measurement goals around each of those areas of measurement. We believe the number of bonus points provides extra credit for submitting the measure, yet would not mask poor performance on the measure. For example, a MIPS eligible clinician with poor outcomes receives only two points for performance for a particular high priority measure. The bonus points would increase the MIPS eligible clinician's points to three (or four if the measure is an outcome measure or patient experience measure), but that amount is far less than the ten points a top performer would receive. We note that population-based measures would not receive bonus points.

We note that a MIPS eligible clinician who submits a high priority measure but had a performance rate of 0 percent would not receive any bonus points. Eligible clinicians would only receive bonus points if the performance rate is greater than zero. Bonus points are also available for measures that are not scored (not included in the top 6 measures for the quality performance category score) as long as the measure has the required case minimum and data completeness. We believe these qualities would allow us to include the measure in future benchmark development.

For groups submitting data through the CMS Web Interface, including MIPS APMs that report through the CMS Web Interface, groups are required to submit a set of predetermined measures and groups are unable to submit additional measures. For that submission mechanism, we propose to apply bonus points based on the finalized set of measures. We would assign two bonus points for each outcome measure (after the first required outcome measure) and for each patient experience measure. We would also have one additional bonus point for each other high priority measure (patient safety, efficiency, appropriate use, care coordination). We believe MIPS eligible clinicians or groups should have the ability to receive bonus points for reporting high priority measures through all submission mechanisms, including the CMS Web Interface. In the final rule, we will publish how many bonus points the CMS Web Interface measure set would have available based on the final list of measures.

We propose to cap the bonus points for the high priority measures (outcome, appropriate use, patient safety, efficiency, patient experience, and care coordination measures) at 5 percent of the denominator of the quality performance category score. Tables 19 and 20 illustrate examples of how to calculate the bonus cap. We also propose an alternative approach of capping bonus points for high priority measures at 10 percent of the denominator of the quality performance category score. Our rationale for the 5 percent cap is that we do not want to mask poor performance by allowing an MIPS eligible clinician to perform poorly on a measure but still obtain a high quality performance category score by submitting numerous high priority measures in order to obtain bonus points; however, we are also concerned that 5 percent may not be enough incentive to encourage reporting. We request comment on the appropriate threshold for this bonus cap.

(f) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act provides that under the methodology for assessing the total performance of each MIPS eligible clinician, the Secretary shall: (I) Encourage MIPS eligible clinicians to report on applicable measures under the quality performance category through the use of CEHRT and QCDRs; and (II) with respect to a performance period for a year, for which a MIPS eligible clinician reports applicable measures under the quality performance category through the use of CEHRT, treat the MIPS eligible clinician as satisfying the clinical quality measures reporting requirement under section 1848(o)(2)(A)(iii) of the Act for such year. To encourage the use of CEHRT for quality improvement and reporting on measures under the quality performance category, we are proposing a scoring incentive to MIPS eligible clinicians who use their CEHRT systems to capture and report quality information.

We propose to allow one bonus point under the quality performance category score, up to a maximum of 5 percent of the denominator of the quality performance category score if:

- The MIPS eligible clinician uses CEHRT to record the measure's demographic and clinical data elements in conformance to the standards relevant for the measure and submission pathway, including but not necessarily limited to the standards included in the CEHRT definition proposed in 414.1305;
- The MIPS eligible clinician exports and transmits measure data electronically to a third party using relevant standards or directly to CMS using a submission method as defined at § 414.1325; and
- The third party intermediary (for example, a QCDR) uses automated software to aggregate measure data, calculate measures, perform any filtering of measurement data, and submit the data electronically to CMS using a submission method as defined at § 414.1325.

These requirements are referred to as "end-to-end electronic reporting."

We note that this bonus would be in addition to the high priority bonus. MIPS eligible clinicians would be eligible for both this bonus option and the high priority bonus option with separate bonus caps for each option. We also propose an alternative approach of capping bonus points for this option at 10 percent of the denominator of the quality performance category score. Our rationale for the 5 percent cap is that we do not want to mask poor performance by allowing a MIPS eligible clinician to perform poorly on a measure but still obtain a high quality performance category score by submitting numerous measures in order to obtain bonus points; however, we are also concerned that 5 percent may not be enough incentive to encourage end-to-end electronic reporting. We seek comment on the appropriate threshold for this bonus cap. We propose the CEHRT bonus would be available to all submission mechanisms except claims submissions. This incentive would also be available for MIPS APMs reporting through the CMS Web Interface. Specifically, MIPS eligible clinicians who report via qualified registries, QCDRs, EHR submission mechanisms, and CMS Web Interface may receive one bonus point for each reported measure with a cap as described. We do not propose to allow this option for claims submission, because there is no mechanism for MIPS eligible clinicians to identify the information was pulled using an EHR.

This approach supports and encourages innovative approaches to measurement using the full array of standards ONC adopts, and the data elements MIPS eligible clinicians capture and exchange, to support patient care. Thus, approaches where a qualified registry or QCDR obtains data from a MIPS eligible clinician's CEHRT using any of the wide range of ONC-adopted standards and then uses automated electronic systems to perform aggregation, calculation, filtering, and reporting would qualify each such measure for the CEHRT bonus point. In addition, measures submitted using the EHR submission mechanism or the EHR submission mechanism through a third party would also qualify for the CEHRT bonus.

We request comment on this proposed approach.

(g) Calculating the Quality Performance Category Score

The next two subsections provide a detailed description of how the quality performance category score would be calculated under our proposals.

(i) Calculating the Quality Performance Category Score for Non-APM Entity, Non-CMS Web Interface Reporters

To calculate the quality performance category score, we propose at § 414.1380(b)(1)(xv) to sum the weighted points assigned for the measures required by the quality performance category criteria plus the bonus points and divide by the weighted sum of total possible points.

If a MIPS eligible clinician elects to report more than the minimum number of measures to meet the MIPS quality performance category criteria, then we would only include the scores for the measures with the highest number of assigned points. For example, if a patient facing MIPS eligible clinician's quality submission criteria is to report six measures with at least one cross-cutting measure and a high priority measure, and the MIPS eligible clinician reports eight process measures (three using CEHRT), one cross-cutting measure, and one outcome measure, then we propose to use the four process measures with the highest number of assigned points, plus the cross-cutting measure and the outcome measure, in addition to the two population-based measures (the all-cause readmission measure would not apply to an MIPS eligible clinician reporting individually), to calculate the quality performance category score. Allowing MIPS eligible clinicians to report additional measures without including them in the scoring allows MIPS eligible clinicians to become familiar with new measures and gain experience with those measures. It also provides the foundation for the MIPS eligible clinician to receive credit for improvement on those measures in future years.

If a MIPS eligible clinician has met the quality performance category submission criteria for reporting quality information, but does not have any scored measures as discussed in section II.E.6.b.2., then a quality performance category score would not be calculated. Refer to section II.E.6.a.2.d. for details on how we propose to address scenarios where a quality performance category score is not calculated for a MIPS eligible clinician.

The following example illustrates a sample scoring methodology. In this scenario, a MIPS eligible clinician submits individually via registry three process measures, one outcome measure, and one other high priority measure. Two of the process measures and one outcome measure qualify for the CEHRT bonus. The patient facing MIPS eligible clinician did not submit on an expected cross-cutting measure and therefore would receive zero points for that requirement. Measures that do not meet the required case minimum or do not have a benchmark are not used for scoring. We reiterate that a measure that is not scored due to not meeting the required case minimum or lack of a measure benchmark would be treated differently than a required measure that is not reported. Any required measure that is not reported, or reported in a way that does not meet the data completeness requirements, would receive a score of zero points and be considered a scored measure. Table 19 illustrates the example.

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TABLE 19: Quality Performance Category Example with High Priority and CEHRT Bonus Points

Measure	Measure Type	Number of Cases	Points Based on Performance	Total Possible Points	Quality Bonus Points For High Priority	Quality Bonus Points for CEHRT
Measure 1	Outcome Measure using CEHRT	20	4.1	10	0 (required)	1
Measure 2	Process using CEHRT	21	9.3	10	N/A	1
Measure 3	Process via CEHRT	22	10	10	N/A	1
Measure 4	Process	50	10	10	N/A	N/A
Measure 5	High Priority-Patient Safety	43	8.5	10	1	N/A
Measure 6 (Missing)	Cross-Cutting	N/A	0	10	N/A	N/A
Acute Composite	Claims	10	Not scored: below required case minimum	N/A	N/A	N/A
Chronic Composite	Claims	20	6.3	10	N/A	N/A
All-Cause Hospital Readmission	Claims	N/A to individual eligible clinicians	N/A	N/A	N/A	N/A
Total Points	All Measures	N/A	48.2	70	1	3

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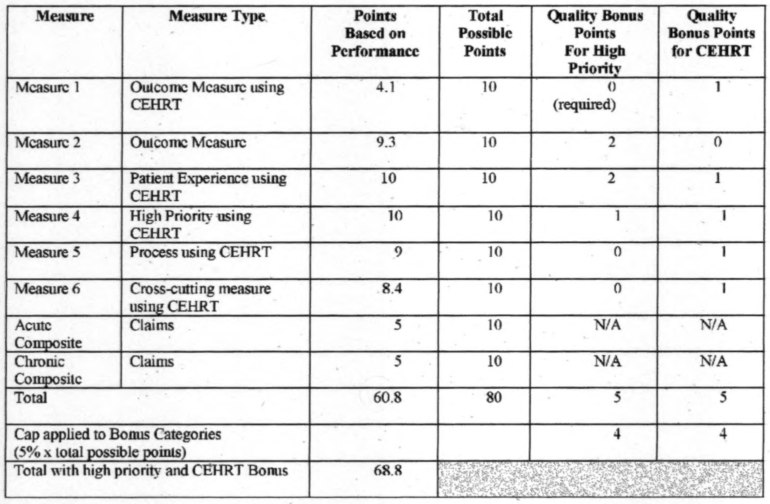
The total possible points for the eligible clinician is 70 points. The eligible clinician has 48.2 points based on performance. The eligible clinician also qualifies for one bonus point for reporting an additional high priority patient safety measure and three bonus points for end-to-end electronic reporting of quality measures. The bonus points for high priority measures and CEHRT reporting are both under two separate caps which is 5 percent of 70 possible points or 3.5 points per bonus category). The quality performance category score for this MIPS eligible clinician is (48.2 points + 4 bonus points = 52.2)/70 total possible points = 74.6 percent. The quality performance category score would be capped at 100 percent.

The following example in Table 20 illustrates how to calculate the bonus cap for the high priority measure bonus and the CEHRT bonus. In the scenario below, the MIPS eligible clinician has submitted six measures and would also be scored on two of the three population-based measures. The MIPS eligible clinician below successfully submitted five quality measures using end-to-end electronic reporting, and therefore, qualifies for the CEHRT bonus of one point for each of those measures. In addition to CEHRT bonus points, the MIPS eligible clinician reported outcome measures for high priority bonus points. The MIPS eligible clinician reported two outcome measures and receives two bonus points for the second outcome measure, given that no bonus points are given for the first required measure. However, both bonus categories are over the cap (which is 5 percent of 80 possible points or four points per bonus category). The quality performance category score for this MIPS eligible clinician is 68.8 (60.8 + 4 CEHRT bonus points after the cap + 4 high priority bonus points after the cap) or 86 percent (68.8/80). Note, in section II.E.5.b.(2), we propose to weight the quality performance category at 50 percent of the MIPS CPS, so an 86 percent quality performance category score would account for 50 percent of the CPS.

TABLE 20: Quality Performance Category Bonus Cap Example



Measure	Measure Type	Points Based on Performance	Total Possible Points	Quality Bonus Points For High Priority	Quality Bonus Points for CEHRT
Measure 1	Outcome Measure using CEHRT	4.1	10	0 (required)	1
Measure 2	Outcome Measure	9.3	10	2	0
Measure 3	Patient Experience using CEHRT	10	10	2	1
Measure 4	High Priority using CEHRT	10	10	1	1
Measure 5	Process using CEHRT	9	10	0	1
Measure 6	Cross-cutting measure using CEHRT	8.4	10	0	1
Acute Composite	Claims	5	10	N/A	N/A
Chronic Composite	Claims	5	10	N/A	N/A
Total		60.8	80	5	5
Cap applied to Bonus Categories (5% x total possible points)				4	4
Total with high priority and CEHRT Bonus		68.8	▨	▨	▨

We request comment on our proposals to calculate the quality performance category score.

(ii) Calculating the Quality Performance Category for CMS Web Interface Reporters

CMS Web Interface reporters have different quality performance category submission criteria; therefore, we propose to modify our scoring logic slightly to accommodate this submission mechanism. CMS Web Interface users report on the entire set of measures specified for that mechanism. Therefore, rather than scoring the top six reported measures, we propose to score all measures. If a group does not meet the reporting requirements for one of the measures, then the group would receive zero points for that measure. We note that since groups reporting through the Web Interface are required to report on all measures, and since some of those measures are "high priority," these groups would always have some bonus points for the quality performance category score if all the measures are reported. That is, the group would either report on less than all web interface measures, in which case the group would receive zeros for unreported measures, or the group would report on all measures, in which case the group would automatically be eligible for bonus points. The other proposals for scoring discussed in section II.E.6.a.2.g.i., including bonus points, would still apply for CMS Web Interface. We request comment on this proposal.

(h) Measuring Improvement

Section 1848(q)(3)(B) of the Act requires the Secretary, in establishing performance standards for measures and activities for the MIPS performance categories, to consider: Historical performance standards; improvement; and the opportunity for continued improvement. In addition, under section 1848(q)(5)(D) of the Act, beginning with the second year of the MIPS, if data sufficient to measure improvement are available, the CPS methodology shall take into account improvement of the MIPS eligible clinician in calculating the performance score for the quality and resource use performance categories and may take into account improvement for the CPIA and advancing care information performance categories.

We are soliciting public comments on potential ways to incorporate improvement into the scoring methodology moving forward. We are especially interested in feedback on the following three options, with the assumption that eligible clinicians would report the same measures year-to-year (where possible). We are also interested in feedback on how to score improvement given that a MIPS eligible clinician can change measures and submission mechanisms from year-to-year. In addition, a MIPS eligible clinician can elect to report as an individual or a member of a group and that election can vary from year to year. Finally, we seek feedback on whether to score improvement where MIPS eligible clinicians do not have the required case minimum for measures to be scored.

Option 1: We could adopt the approach for assessing improvement currently used for the HVBP, where we assign from 1–10 points for achievement and from 1–9 points for improvement for each measure. We would compare the achievement and improvement points for each measure in the quality performance category and score whichever is greater. Specifically, we would determine two scores for a MIPS eligible clinician at the measure level for the quality performance category. First, we would assess the MIPS eligible clinician's achievement score, which measures how the MIPS eligible clinician performed compared to benchmark performance scores for each applicable measure in the quality performance category. Second, we would assess the MIPS eligible clinician's improvement score, which measures how much a MIPS eligible clinician has improved compared to the MIPS eligible clinician's own previous performance during a baseline period for each applicable measure in the quality performance category. Under this methodology, we would compare the achievement and improvement scores for each measure and only use whichever is greater, but only those eligible clinicians with the top achievement would be able to receive the maximum number of points. If a MIPS eligible clinician's practice was not open during the baseline period but was open during the performance period, points would be awarded based on achievement only for that performance period. For a more detailed description of the HVBP methodology, we refer readers to § 412.160 and § 412.165.

Option 2: We could adopt the approach for assessing improvement currently used in the Shared Savings Program, where eligible clinicians or groups would receive a certain number of bonus points for the quality performance category for improvement, although the total points received for the performance may not exceed the maximum total points for the performance category in the absence of the quality improvement points. Under this methodology, we would score individual measures and determine the corresponding number of points that may be earned based on the MIPS eligible clinician's performance. We would add the points earned for the individual measures within the quality performance category and divide by the total points available for the performance category to determine the quality performance category score. MIPS eligible clinicians that demonstrate quality improvement on established quality measures from year-to-year would be eligible for up to four bonus points for the quality performance category. Bonus points would be awarded based on a MIPS eligible clinician's net improvement in measures within the quality performance category, which would be calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures. Up to four bonus points would be awarded based on a comparison of the MIPS eligible clinician's net improvement in performance on the measures to the total number of individual measures in the quality performance category. When bonus points are added to points earned for the quality measures in the quality performance category, the total points received for the quality performance category may not exceed the maximum total points for the performance category in the absence of the quality improvement points. For a more detailed description of the Shared Savings Program methodology, we refer readers to § 425.502, as well as CY 2015 PFS final rule with comment (79 FR 67928–67931) for a discussion of how CMS will determine whether the improvement or decline is significant.

Option 3: We could adopt the approach similar to that for assessing improvement for the Medicare Advantage 5-star rating methodology. Under this approach, we would identify an overall "improvement measure score" by comparing the underlying numeric data for measures from the prior year with the data from measures for the performance period. To obtain an "improvement measure score" MIPS eligible clinicians would need to have data for both years in at least half of the required measures for the quality performance category. The numerator for the overall "improvement measure" would be the net improvement, which is a sum of the number of significantly improved measures minus the number of significantly declined measures. The denominator is the number of measures eligible for improvement since to qualify for use in the "improvement measure" calculation, a measure must exist in both years and not have had a significant change in its specification. This "improvement measure" would be included in the quality performance category. We recognize that high performing MIPS eligible clinicians may have less room for improvement and consequently may have lower scores on the overall "improvement measure". Therefore, under this option we would propose the following rule, which is similar to how the 5-star rating methodology treats highly rated plans in connection with the improvement measure to avoid penalizing consistently high-performing eligible clinicians: We would calculate a MIPS eligible clinician's score with the "improvement measure" and without, and use the MIPS eligible clinician's best score. We request comments on these proposals.

(3) Scoring the Resource Use Performance Category

As we described in section II.E.6.a.1. of this rule, we proposed to align scoring across the MIPS performance categories. For the resource use performance category, we propose to score the resource use measures similarly to the quality performance category. Specifically, we propose at § 414.1380(b)(2) to assign one to ten points to each measure based on a MIPS eligible clinician's performance compared to a benchmark. However, we note that for the resource use performance category (unlike the quality performance category), the benchmark is based on the performance period, rather than the baseline period. The details of the scoring for resource use measures are described below.

(a) Resource Use Measure Benchmarks

For the resource use performance category, we propose at § 414.1380(b)(2) that the performance standard is measure-specific benchmarks. We would calculate an array of measure benchmarks based on performance. Then, a MIPS eligible clinician's actual measure performance during the performance period would be evaluated to determine the number of points that should be assigned based on where the actual measure performance falls within these benchmarks.

We propose at § 414.1380(b)(2) to create benchmarks for the resource use measures based on the performance period. Changes in payment policies, including changes in relative value units, and changes that affect how hospitals, clinicians and other health care providers are paid under Medicare Parts A and B, can make it challenging to compare resource use in a performance period with a historical baseline period. In addition, for HVBP and VM, we use the performance period to establish the benchmarks for scoring HVBP's efficiency measures and VM's cost measures (80 FR 49562, 80 FR 71280). If we use the performance period, we would publish the benchmark methodology in a final rule, but would not be able to publish the actual numerical benchmarks in advance of the performance period. We believe that it is important for MIPS eligible clinicians to know in advance how they might be scored and can track their performance so we would continue to provide performance feedback with information on the MIPS eligible clinician's relative performance.

We considered an alternative to base the resource use performance category measure benchmarks on the baseline period proposed in section II.E.6.a.1.c., rather than the performance period. This option would further align the resource use performance category benchmark methodology with the quality performance category benchmark methodology. This option would also allow us to publish the numerical benchmarks before the performance period ends; however, we believe the benefits of earlier published benchmarks are more limited for resource use measures. MIPS eligible clinicians would not be able to track their daily progress because they would not have all the necessary information to determine the attribution, price standardization, and otherwise adjust the measures. We believe the relative performance that we provide through feedback reports would provide MIPS eligible clinicians the information they need to track performance and to learn about their resource utilization. In addition, we believe that using benchmarks based in the performance period is a better approach than using benchmarks based in the baseline period because different payment policies could apply during the baseline period than during the performance period which could affect a MIPS' eligible clinician's resource use. We would also have to identify the baseline benchmark and trend it forward so that the dollars in the baseline period are comparable to the performance period, whereas we would not have to make a trending adjustment for benchmarks based on the performance period. For these reasons, we elected to propose to base the benchmarks on the performance period rather than the baseline period.

We propose to create a single set of benchmarks for each measure specified for the resource use performance category. All MIPS eligible clinicians that are attributed sufficient cases for the measure would be included in the same benchmark. In addition, we would require a minimum of 20 MIPS eligible clinicians or groups to be attributed the case minimum in order to develop the benchmark. If a measure does not have enough eligible clinicians or groups that are attributed enough cases to create a benchmark, then we would not include that measure in the scoring for the resource use performance category.

We request comment on the proposal to establish resource use measure benchmarks based on the performance period as well as the alternative proposal.

(b) Assigning Points Based on Achievement

For each set of benchmarks, we propose to calculate the decile breaks based on measure performance during the performance period and assign points for a measure based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. We propose that for resource use measures, lower costs represent better performance. In other words, MIPS eligible clinicians in the top decile would have the lowest resource use. We propose to use a methodology generally consistent with the methodology proposed for the quality performance category. We refer readers to Tables 21 and 22 for details on assigning points based on decile distribution. We request comments on the methodology for assigning points based on performance period deciles for the resource use performance category and solicit comments on alternative methodologies for assigning points for performance under this performance category for future rulemaking.

Table 21 illustrates an example of using decile points along with partial points to assign achievement points for a sample resource use measure.

TABLE 21: Example of Using Benchmarks for One Sample Measure to Assign Points

Decile	Average Resource Use	Possible Points
Benchmark Decile 1	$100,000 or more	1.0-1.9
Benchmark Decile 2	$75,893-$99,999	2.0-2.9
Benchmark Decile 3	$69,003-$75,892	3.0-3.9
Benchmark Decile 4	$56,009-$69,002	4.0-4.9
Benchmark Decile 5	$50,300-$56,008	5.0-5.9
Benchmark Decile 6	$34,544-$50,299	6.0-6.9
Benchmark Decile 7	$27,900-$34,543	7.0-7.9
Benchmark Decile 8	$21,656-$27,899	8.0-8.9
Benchmark Decile 9	$15,001-$21,655	9.0-9.9
Benchmark Decile 10	$1,000-$15,000	10

Note: The numbers provided in this table are for illustrative purposes only.

(c) Case Minimum Requirements

We seek to ensure that MIPS eligible clinicians are measured reliably; therefore, we proposed in section II.E.5.e.3. to establish a 20 case minimum for each resource use measure. We note that this would include the Medicare Spending Per Beneficiary (MSPB) measure. In the CY 2016 PFS final rule, we finalized a policy that increases the required case minimum for MSPB from 20 to 125 cases (80 FR 71295–71296). However, due to the proposed changes to the MSPB measure, discussed in section II.E.5.e.(3)(a)., we believe we can appropriately use a required case minimum of 20 for the revised MSPB measure. Refer to section II.E.5.e.(3) for our rationale for this proposal.

(d) Calculating the Resource Use Performance Category Score

To calculate the resource use performance category score, we propose at § 414.1380(b)(2)(iii) to average all the scores of all the resource use measures attributed to the MIPS eligible clinician. All measures in the resource use performance category as described in section II.E.5.e would be weighted equally. If a MIPS eligible clinician has only one resource use measure with a required case minimum to be scored, we would score that measure accordingly, and the MIPS eligible clinician's resource use performance category score would consist of the score for that one measure. We note that MIPS eligible clinicians cannot receive a zero score for any resource use measure for failure to submit the measure since none of the resource use performance category measures are submitted by MIPS eligible clinicians. Rather, these measures are attributed to MIPS eligible clinicians through claims data. However, if a MIPS eligible clinician is not attributed any resource use measures (for example, because the case minimum requirements have not been met for any measure or there is not a sufficient number of MIPS eligible clinicians to create a benchmark for any measure), then a resource use performance category score would not be calculated. Refer to section II.E.6.b for details on how we propose to address scenarios where a performance category score is not calculated for a MIPS eligible clinician. MIPS eligible clinicians would receive performance feedback as required under section 1848(q)(12) of the Act and discussed in section II.E.8.a of this proposed rule. Over time, performance feedback may include a list of attributed cases for each measure by MIPS eligible clinician. We request comment on our proposals to calculate the resource use performance category score.

Table 22 illustrates a sample scoring methodology for a limited set of measures. A MIPS eligible clinician is attributed resource use measures as described above and receives a score for measures where the eligible clinician has a sufficient number of cases attributed.

The MIPS eligible clinician described in Table 22 did not have the required case minimum for Measure 4 (Episode 2), and therefore is not scored on this measure. Similarly, the MIPS eligible clinician was not attributed any cases for Measure 5 (Episode 3) and was not scored on the measure. Measures that do not meet the required case minimum are not used for scoring.

TABLE 22: Resource Use Performance Category Example

Measure	Measure Type	Number of Cases (min. 20)	Performance ($)	Median Performance ($)	Points	Total Possible
Measure 1	MSPB	20	15,000	13,000	4.0	10
Measure 2	Total Per Capita	21	12,000	10,000	4.2	10
Measure 3	Episode 1	22	15,000	18,000	5.8	10
Measure 4	Episode 2	10	11,000	9,000	Below Case Threshold	N/A
Measure 5	Episode 3	0	N/A	N/A	No Attributed Cases	N/A
Measure 6	Episode 4	45	7,000	10,000	8.3	10
Total Points					22.3	40

In the example above, making the assumption that all measures listed have a median performance falling between the fifth and sixth deciles and would provide a score of six points, the MIPS eligible clinician with a value above the median would receive a score lower than six points. For example, Measure 1 has a performance of $15,000 which is higher than the median performance of $13,000, therefore the number of points assigned (4.0) is lower than six points.

Based on the resource use measures available for scoring, the MIPS eligible clinician is scored against the total number of points available. The resource use performance category score for this eligible clinician is (22.3 performance points/40 possible points) = 55.8 percent.

Unlike the quality performance category score, we are not proposing bonus points as part of the resource use performance category score.

(4) Scoring the CPIA Performance Category

Section 1848(q)(5)(C) of the Act outlines specific scoring rules for the CPIA performance category. Section 1848(q)(5)(C)(i) of the Act provides that a MIPS eligible clinician who is in a practice that is certified as a patient-centered medical home or comparable specialty practice with respect to a performance period shall receive the highest potential score for the CPIA performance category for such period. Section 1848(q)(5)(C)(ii) of the Act provides that MIPS eligible clinicians participating in an APM with respect to a performance period shall earn a minimum score of one-half of the highest potential score for the CPIA performance category for such period. We refer readers to section II.E.5.h of this preamble for a description of the APM scoring standard. Section 1848(q)(5)(C)(iii) of the Act states that MIPS eligible clinicians are not required to perform activities in each subcategory or participate in an APM in order to receive the highest possible score for the CPIA performance category. Based on these criteria, we propose a scoring methodology that assigns points for the CPIA performance category (based on patient-centered medical home participation and the CPIAs reported by the MIPS eligible clinician). A MIPS eligible clinician's performance would be evaluated by comparing the reported CPIAs to the highest possible score.

(a) Assigning Points to Reported CPIAs

CPIA is a new performance category that has not been implemented in our previous programs. Therefore, in year 1, we cannot assess how well the MIPS eligible clinician has performed on the activity against data from a baseline year. We can only assess whether the MIPS eligible clinician has participated sufficiently to receive credit in the CPIA performance category. Therefore, we propose at § 414.1380(b)(3) to assign points for each reported activity within two categories: Medium-weighted and high-weighted activities. Medium-weighted activities are worth 10 points. High-weighted activities are worth 20 points. Table 23 lists all of the proposed CPIAs that are high-weighted. All other activities not listed as high-weighted activities would be considered medium activities. Table H in the Appendices provides the CPIA Inventory of all activities, both medium-weighted and high-weighted. Consistent with our unified scoring system principles, MIPS eligible clinicians would know in advance how many potential points they could receive for each CPIA.

Activities are proposed to be weighted as high based on the extent to which they align with activities that support the patient-centered model home, since that is the standard under section 1848(q)(5)(C)(i) of the Act for achieving the highest potential score for the CPIA performance category, as well as with CMS priorities for transforming clinical practice. Additionally, activities that require performance of multiple actions, such as participation in the

Transforming Clinical Practice Initiative, participation in a MIPS eligible clinician's state Medicaid program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) are justifiably weighted as high. We seek comment on which activities should receive a high weight as opposed to a medium weight.

We also considered an approach of equal weighting for all CPIAs. We seek comment on a multi-tier weighting approach such as low, medium and high activity categories for future years of MIPS.

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TABLE 23: CPIAs with a High Weight

Subcategory	Activity	Weighting
Expanded Practice Access	Provide 24/7 access to MIPS eligible clinicians, eligible groups, or care teams for advice about urgent and emergent care (e.g., eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); Use of alternatives to increase access to care team by MIPS eligible clinicians and MIPS eligible groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.	High
Population Management	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, patient self-management program) for 60 percent of practice patients in year 1 and 75 percent of practice patients in year 2 who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).	High
Population Management	MIPS eligible clinicians and MIPS eligible clinician groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, in the first performance period, 60 percent or more of their ambulatory care patients receiving warfarin are being managed by one or more of these clinical practice improvement activities: Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing,	High

Subcategory	Activity	Weighting
	tracking, follow-up, and patient communication of results and dosing decisions; For rural or remote patient, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; and/or For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program. The performance threshold will increase to 75 percent for the second performance period and onward. Clinicians would attest that, 60 percent for the first year, or 75 percent for the second year, of their ambulatory care patients receiving warfarin participated in an anticoagulation management program for at least 90 days during the performance period.	
Population Management	For outpatient Medicare beneficiaries with diabetes and who are prescribed antidiabetic agents (e.g., insulin, sulfonylureas), MIPS eligible clinicians and MIPS eligible clinician groups must attest to having: For the first performance period, at least 60 percent of medical records with documentation of an individualized glycemic treatment goal that: a) Takes into account patient-specific factors, including, at least age, comorbidities, and risk for hypoglycemia; and b) Is reassessed at least annually. The performance threshold will increase to 75 percent for the second performance period and onward. Clinicians would attest that, 60 percent for the first year, or 75 percent for the second year, of their medical records that document individualized glycemic treatment represent patients who are being treated for at least 90 days during the performance period.	High
Population Management	Use of a Qualified Clinical Data Registry to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.	High

Subcategory	Activity	Weighting
Care Coordination	Participation in the CMS Transforming Clinical Practice Initiative.	High
Beneficiary Engagement	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.	High
Patient Safety and Practice Assessment	Consultation of **Prescription Drug Monitoring Program** prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription that lasts for longer than three days.	High
Achieving Health Equity	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare.	High
Integrated Behavioral and Mental Health	Integration facilitation, and promotion of the colocation of mental health services in primary and/or non-primary clinical care settings.	High
Integrated Behavioral and Mental Health	• Offer integrated behavioral health services to support patients with behavioral health needs, dementia, and poorly controlled chronic conditions that could include one or more of the following: Use evidence-based treatment protocols and treatment to goal where appropriate; Use evidence-based screening and case finding strategies to identify individuals at risk and in need of services; Ensure regular communication and coordinated workflows between eligible clinicians in primary care and behavioral health; Conduct regular case reviews for at-risk or unstable patients and those who are not responding to treatment; Use of a registry or other certified health information technology functionality to support active care management and outreach to patients in treatment; and/or Integrate behavioral health and medical care plans and facilitate integration through co-location of services when feasible.	High

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(b) CPIA Performance Category Highest Potential Score

Although there is variability in the level that each MIPS eligible clinician would perform a CPIA, we currently do not have a standard way of measuring that variability. In future years, we plan to capture data to begin to develop a baseline for measuring CPIA improvement. Because we cannot measure variable performance within a CPIA, we propose at § 414.1380(b)(3)(v) to compare the points associated with the reported activities against the highest potential score. We propose the highest potential score to be 60 points for the CY 2017 performance period given the following rationale.

Based on discussions with several high performing organizations, we believe that MIPS eligible clinicians would be able to report on as many as six activities of medium weight. Examples of these organizations include one that led a major redesign of patient workflow after Hurricane Katrina, implementing clinical practice improvements to ensure patients receive faster treatment in the event of future disasters, ranked nationally in 6 adult specialties and high-performing in 6 adult specialties;[16] a second that was recognized by a leading medical association that achieved: 6.7 percent 30-day all cause readmissions, 42 percent fewer ED visits with implementation of a 60-day intensive home care program, costs of 15 percent-28 percent below regional average and significant improvement in patient surveys from CAHPS;[17] and a third recognized as a leader in rural health with the highest award for excellence from the National Rural Primary Care Association.

We also believe that a top performing small practice (consisting of 15 or fewer professionals) or practice in a rural or health professional shortage area, or a non-patient facing MIPS eligible clinician would be able to report on at least two activities. In consideration of special circumstances for these small practices, as well as practices located in rural areas and in Health Professional Shortage Areas (HPSAs) or non-patient facing MIPS eligible clinicians, we propose that the weight for any activity selected would be 30 points. For any MIPS eligible clinician, the maximum total points achievable in this performance category is 60 points. Based on the above rationale, we believe it is reasonable to expect all MIPS eligible clinicians to be able to report CPIAs, and as such, a MIPS eligible clinician reporting no CPIA would receive a zero score for the CPIA performance category. We believe this proposal allows us to capture variation in reporting the CPIA performance category.

(c) Points for Certified Patient-Centered Medical Home or Comparable Specialty Practice

Section 1848(q)(5)(C)(i) of the Act specifies that a MIPS eligible clinician who is in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, with respect to a performance period must be given the highest potential score for the CPIA performance category for the performance period. We propose that patient-centered medical home practices are those that have received accreditation from any of the following four nationally recognized accreditation organizations (the Accreditation Association for Ambulatory Health Care, the National Committee for Quality Assurance (NCQA), The Joint Commission, and the Utilization Review Accreditation Commission (URAC));[18] or are a Medicaid Medical Home Model or Medical Home Model. We propose that CMS's proposed comparable specialty practices are those that include the NCQA Patient-Centered Specialty Recognition. We refer readers to section II.F. of this proposed rule for further description of the Medicaid Medical Home Model or Medical Home Model. The four accreditation organizations listed above all have evidence of being used by a large number of medical organizations as the model for their patient-centered medical home and are national in scope. No other criteria are required for receiving recognition as a certified patient patient-centered medical home or comparable specialty practice except for being recognized by one of the above organizations.

Section II.E.5.f. of this rule outlines the policy for certified patient-centered medical homes. The organizations identified above maintain a list of certified patient-centered medical homes, including the Medicaid Medical Home and Medical Home Models, that would be used to determine whether a MIPS eligible clinician qualifies for the highest potential score for the CPIA performance category because the MIPS eligible clinician is in a certified patient-centered medical home. NCQA maintains a list of practices that have received the Patient-Centered Specialty Recognition which would be used to determine whether a MIPS eligible clinician qualifies for the highest potential score for the CPIA performance category because the MIPS eligible clinician is in a comparable specialty practice.

We propose at § 414.1380(b)(3) that a MIPS eligible clinician who is in a practice that is certified as a patient-centered medical home, including a Medicaid Medical Home or Medical Home Model, or comparable specialty practice in accordance with those proposals would receive the highest potential score (in accordance with section 1848(q)(5)(C)(i) of the Act) of 60 points for the CPIA performance category.

(1) Section II.E.5.f. of this rule presents the CMS Study on CPIA and Measurement. Given the burden for participants completing the year-long study and the value of collectively examining innovation and practice activities to improve clinical quality data submissions and further reduce time requirements for eligible clinicians and groups to report, we propose that MIPS eligible clinicians and groups that successfully participate and submit data to fulfill study requirements would receive the highest potential score of 60 points for the CPIA performance category.

(d) Calculating the CPIA Performance Category Score

To determine the CPIA performance category score, we propose to sum the points for all of the MIPS eligible clinician's reported activities and divide by the proposed CPIA performance category highest potential score of 60. A perfect score would be 60 points divided by 60 possible points, which equals 100 percent. If MIPS eligible clinicians have more than 60 CPIA points, then we propose to cap the resulting CPIA performance category score at 100 percent.

Table 24 illustrates a sample scoring methodology for the CPIA performance category. The MIPS eligible clinician below was not an APM participant and does not immediately earn the minimum score of one-half of the highest potential score or 30 points that are available for APM participation. The MIPS eligible clinician below completed two high-weighted activities worth 20 points each and two medium-weighted activities for 10 points each in order to receive the maximum 60 points available in the performance category for a CPIA performance category score of 100 percent.

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[16] U.S. News and World Report 2015–2016 Best Hospitals Ranking. Retrieved from *https://www.ochsner.org/patients-visitors/about-us/outcomes-and-honors/us-news-and-world-report.*

[17] California Association of Physicians Groups in Medicare Advantage (2014). Retrieved from *http://www.ehcca.com/presentations/capgma1/cohen_b2.pdf.*

[18] The name was officially shortened to URAC in 1996.

TABLE 24: CPIA Performance Category Scoring Example

Activity	Subcategory	Points	Relative Weight (High = 2 Medium = 1)	Points	Total Possible Points (fixed)
Activity 1	Expanded Practice Access	10	2	20	
Activity 2	Population Management	10	2	20	
Activity 3	Integrated Behavioral and Mental Health	10	1	10	
Activity 4	Achieving Health Equity	10	1	10	
Total Points				60	60

Alternatively, the MIPS eligible clinician could have selected three high-weighted activities for 20 points each, six medium-weighted activities for ten points each, or some combination to reach 60 points. The score however is capped at 100 percent (60/60). This means that a MIPS eligible clinician who selects four high-weight activities (80 possible points) would still be given a score of 100 percent (60/60).

Section 1848(q)(2)(B)(iii) of the Act requires the Secretary to give consideration to the circumstances of small practices (consisting of 15 or fewer professionals) and practices located in rural areas and in geographic health professional shortage areas (HPSAs) (as designated under section 332(a)(1)(A) of the Public Health Service Act) in defining activities. Section 1848(q)(2)(C)(iv) of the Act also requires the Secretary to give consideration to non-patient-facing MIPS eligible clinicians. Further, section 1848(q)(F)(5) of the Act allows the Secretary to assign different scoring weights for measures, activities, and performance categories, if there are not sufficient measures and activities applicable and available to each type of eligible clinician.

For MIPS eligible clinicians and groups that are small practices (consisting of 15 or fewer professionals), practices located in rural areas, practices located in geographic HPSAs, or non-patient facing MIPS eligible clinicians or non-patient facing MIPS eligible clinician groups, we propose alternative scoring requirements for the CPIA performance category. The rationale for this alternative scoring is grounded in the resource constraints these MIPS eligible clinicians face which was further discovered during listening sessions with small, rural and geographic HPSAs and medical societies for non-patient facing MIPS eligible clinicians and groups. We believe that while non-patient facing MIPS eligible clinicians and non-patient facing groups could select activities from some sub-categories (such as care coordination and patient safety), for other sub-categories (such as beneficiary engagement and population management) non-patient facing MIPS eligible clinicians and groups will need to consider novel practice activities that are within their scope and can improve beneficiary care. We will continue to work with non-patient facing MIPS eligible clinician professional organizations to further develop activities relevant for these clinicians in future years. Our rationale for small practices and practices located in rural areas and in HPSAs is grounded in the resource constraints that these MIPS eligible clinicians face. This rationale is especially compelling given that each activity requires at least 90 days and may not necessarily be conducted in parallel, with time allocated to pre-planning and post-planning, which would impact the practice's limited resources.

All MIPS eligible clinicians would be allowed to self-identify as part of an APM, a patient-centered medical home or comparable specialty practice, a Medicaid Medical Home or Medical Home Model, a non-patient facing professional, a small practice (consisting of 15 or fewer professionals), a practice located in a rural area, or a practice in a geographic HPSA or any combination thereof as applicable during attestation following the performance period. We refer readers to *https://innovation.cms.gov/Medicare-Demonstrations/Medicare-Medical-Home-Demonstration.html* for more information on the Medical Home Model.

We would validate these self-identifications as appropriate. We propose that the following scoring would apply to MIPS eligible clinicians who are a non-patient facing professional, a small practice (consisting of 15 or fewer professionals), a practice located in a rural area, or practice in a geographic HPSA or any combination thereof:

- Reporting of one medium-weighted or high-weighted activity would result in 50 percent of the highest potential score.
- Reporting of two medium-weighted or high-weighted activities would result in 100 percent of the highest potential score.

In future years, we may adjust the weighting of activities at the MIPS eligible clinician level based on initial patterns of CPIA reporting. For example, if a MIPS eligible clinician reports on the same medium-weighted activity over several performance periods, in a subsequent year that MIPS eligible clinician may not be allowed to continue to select that same activity. This is because the intent of the CPIA performance category is to demonstrate improvement over time and not just demonstrate same benefit from year to year. For example, continuing to provide expanded practice access does not demonstrate improvement over time. Further, should the weighting of activities change in future years, we may also adjust the CPIA performance category point target accordingly. We request comment on our proposed approach to score the CPIA performance category. We also seek comment on alternative methodologies for the CPIA performance category. We seek to assure equity in scoring MIPS eligible clinicians while still considering activity variation, impact and burden.

(5) Scoring the Advancing Care Information Performance Category

We refer readers to section II.E.5.g.6. for our proposed methodology for scoring the advancing care information performance category. We reiterate that this methodology has many of the features of the unified scoring system described above. Specifically, we are moving away from the "all-or-nothing" scoring approach of the Medicare EHR Incentive Program. In addition, MIPS eligible clinicians would know in advance what they have to do to achieve points under the advancing care information performance category in MIPS. We provide a brief summary of our proposed scoring methodology here.

In the advancing care information performance category, we propose to score for both participation and performance. We refer to these scoring methods as the "base score" and the "performance score".

To earn points toward the base score, a MIPS eligible clinician or group must report the numerator and denominator (or yes/no statement as applicable) for certain measures adopted by the EHR Incentive Programs in the 2015 EHR Incentive Programs Final Rule to achieve 50 percent of the total advancing care information performance category score. For measures that previously included a percentage-based threshold, we are not requiring MIPS eligible clinicians or groups to meet those thresholds. Instead we propose to require eligible clinicians and groups to report the numerator (of at least one) and denominator (or a yes/no statement for applicable measures) for each measure being reported.

For the base score, MIPS eligible clinicians or groups must meet Objective 1: Protect Patient Health Information and its associated measure in 2015 EHR Incentive Programs Final Rule. Additionally, eligible clinicians would be required to report the numerator and denominator, or a yes/no statement as appropriate, for each measure for Electronic Prescribing, Patient Electronic Access to Health Information, Coordination of Care Through Patient Engagement, Health Information Exchange, and Public Health and Clinical Data Registry Reporting— as adopted in the 2015 EHR Incentive Programs Final Rule. Failure to meet any of the objectives would result in a base score of zero and an advancing care information performance category score of zero.

For the Public Health and Clinical Data Registry Reporting objective, an eligible clinician or group is only required to report on the Immunization Registry Reporting measure. Completing any additional measures under the objective would earn one additional bonus point after calculation of the performance score.

The performance score is then determined in addition to the base score. The performance score methodology would implement a decile scale for the application of additional points based on performance in the objectives and measures for Patient Electronic Access, Coordination of Care through Patient Engagement, and Health Information Exchange. There are eight associated measures under these three objectives; each has a maximum of ten percentage points available. The total available performance score would be 80 percent which is, in combination with the base score of 50 percent, greater than the total possible performance category score of 100 percent. We have taken this approach in order to provide flexibility toward achieving the maximum score in the advancing care information performance category—however, a MIPS eligible clinician or group's score is capped at 100 percent.

This summary only represents the primary advancing care information performance category scoring proposal. For full details on the advancing care information performance category scoring and an explanation of alternatives considered, as well as accommodation for eligible clinicians planning to report Modified Stage 2 or use 2014 Edition CEHRT in 2017 please refer to II.E.5.g.4.

b. Calculating the Composite Performance Score (CPS)

Section II.E.6.a. of this rule describes our proposed methodology for assessing and scoring MIPS eligible clinician performance for each of the four performance categories. In this section, we propose the methodology to determine the CPS based on the scores for each of the four performance categories. We define at § 414.1305 the CPS as a composite assessment (using a scoring scale of 0 to 100) for each MIPS eligible clinician for a specific performance period determined using the methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards with respect to the applicable measures and activities for each applicable performance category. The CPS is the sum of the products of each performance category score and each performance category's assigned weight multiplied by 100.

(1) Formula To Calculate the CPS

Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards with respect to the applicable measures and activities with respect to each performance category applicable to such clinician for a performance period, and using the methodology, provide for a CPS (using a scoring scale of 0 to 100) for each MIPS eligible clinician for the performance period. Additionally, sections 1848(q)(5)(E) and (F) of the Act address the weights for each of the performance categories in the CPS.

To create a CPS from 0–100 based on the individual performance category scores, we propose to multiply the score for each performance category by the assigned weight for the performance category. We provide in Table 25 the weights for each performance category for the 2019, 2020 and 2021 MIPS payment years. The resulting weighted performance category scores would be summed to create a single CPS. As described in section II.E.2 of this preamble, we propose that the identifier for MIPS performance would be the same for all four performance categories, and therefore, the methodology to calculate a CPS would be the same for both individual and group performance.

The following equation summarizes the proposed CPS calculation at § 414.1380(c):

CPS = [(quality performance category score × quality performance category weight) + (resource use performance category score × resource use performance category weight) + (CPIA performance category score × CPIA performance category weight) + (advancing care information performance category score × advancing care information performance category weight)] × 100.

(a) Accounting for Risk Factors

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, that section provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, resource use measures and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, CPSs, scores for performance categories or scores for measures or activities under the MIPS. In doing this, the Secretary is required to take into account the relevant studies conducted and recommendations made in reports under section 2(d) of the Improving Medicare Post-Acute Transformation (IMPACT) Act of 2014 and, as appropriate, other information, including information collected before completion of such studies and recommendations. HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting studies and making recommendations on the issue of risk adjustment for socioeconomic status on quality measures and resource use as required by section 2(d) of the IMPACT Act and expects to issue a report to Congress by October 2016. We will closely examine the recommendations issued by ASPE and incorporate them as feasible and appropriate through future rulemaking. We also note that several MIPS measures, as appropriate, include risk adjustment in their measure specifications. For example, outcome measures in the quality performance category generally have risk adjustment embedded in the measure calculation specification, while process measures generally do not. Similarly, in the resource use performance category, the proposed total per capita costs for all attributed beneficiaries measure is adjusted for demographic and clinical factors. That measure also has a specialty adjustment that is applied after the measure calculation to account for differences in specialty mix within a practice. The MSPB measure and other resource use measures have different risk adjustments that are specific to the individual measure. For the first year of MIPS, for the quality and resource use performance categories, we propose to use the measure-specific risk adjustment for all measures (where applicable), as well as the additional specialty adjustment for the total per capita costs for all attributed beneficiaries.

We invite public comments on this proposal.

(2) CPS Performance Category Weights

(a) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS CPS: In general, 30 percent for the quality performance category, 30 percent for the resource use performance category, 25 percent for the advancing care information performance category, and 15 percent for the CPIA performance category. However, that section also specifies different weightings for the quality and resource use performance categories for the first and second years for which the MIPS applies to payments. Section 1848(q)(5)(E)(i)(II)(bb) of the Act specifies that for year 1, not more than 10 percent of the CPS will be based on the resource use performance category and for year 2, not more than 15 percent will be based on resource use performance category. Under section 1848(q)(5)(E)(i)(I)(bb) of the Act, the weight of the quality performance category for each of the first two years will increase by the difference of 30 percent minus the weight specified for the resource use performance category for the year.

In previous sections of this rule, we have proposed the performance category weights for the first MIPS payment year of 2019. In section II.E.5.e.2., we propose to set the resource use performance category weight at 10 percent for the 2019 payment year and 15 percent for the 2020 payment year. Correspondingly, in section II.E.5.b.2., we propose to set the quality performance category weight to 50 percent for the 2019 payment year and 45 percent for the 2020 payment. The quality performance category weight proposal is based on the 30 percent required by statute for the quality performance category plus 30 percent minus the weight of the resource use performance category, as required by section 1848(q)(5)(E)(i)(I)(bb) of the Act. As specified in section 1848(q)(5)(E)(i) of the Act, the weights for the other performance categories are 25 percent for the advancing care information performance category; and 15 percent for the CPIA performance category. Section 1848(q)(5)(E)(ii) of the Act provides that in any year in which the Secretary estimates that the proportion of eligible professionals (as defined in section 1848(o)(5) of the Act) who are meaningful EHR users (as determined under in section 1848(o)(2) of the Act) is 75 percent or greater, the Secretary may reduce the applicable percentage weight of the advancing care information performance category in the CPS, but not below 15 percent, and adjust the weighting of the other performance categories. We refer readers to our proposals concerning section 1848(q)(5)(E)(ii) of the Act in section II.E.5.g.(6)(e).

Table 25 summarizes the weights specified for each performance category under section 1848(q)(5)(E)(i) of the Act and in accordance with our proposals.

TABLE 25: Weights by Performance Category

Performance Category	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year and beyond
Quality	50%	45%	30%
Resource Use	10%	15%	30%
CPIA	15%	15%	15%
Advancing Care Information*	25%	25%	25%

*The weight for advancing care information could decrease (not below 15 percent) if the Secretary estimates that the proportion of physicians who are meaningful EHR users is 75 percent or greater. The remaining weight would then be reallocated to one or more of the other performance categories.

(b) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable and for each measure and activity based on the extent to which the measure or activity is applicable and available to the type of eligible clinician involved.

In section II.E.6.a and section II.E.5.g.8., we describe scenarios where certain MIPS eligible clinicians might not receive a performance category score in the quality, resource use, or advancing care information performance categories. We propose that in such scenarios we would use the authority under section 1848(q)(5)(F) of the Act to assign a weight of zero to the performance category and redistribute the weight for that performance category or categories as described in the next section.

For the quality and resource use performance categories, we believe having sufficient measures applicable and available means that we are able to reliably calculate a score for the measures that adequately captures and reflects the performance of the MIPS eligible clinician. For the quality and resource use performance categories, we propose in sections II.E.6.a.2.d., II.E.6.3.a., and II.E.6.a.3.d. that we would not calculate a performance category score if a MIPS eligible clinician does not have any measures with the required case minimum or any measures with a sufficient number of MIPS eligible clinicians to create a benchmark. Measures that do not meet the required case minimum or a sufficient number of MIPS eligible clinicians to create a benchmark would be excluded from scoring, and the MIPS eligible clinician would not receive a quality or resource use performance category score. (Note, this situation is different from a MIPS eligible clinician who elects not to submit any quality measures. A MIPS eligible clinician who elects not to submit any quality measures would receive a quality performance category score of zero.) We believe MIPS eligible clinicians who would have no scored measures for a performance category under our proposals would not have sufficient measures applicable and available for that performance category.

For the quality performance category, we anticipate that most MIPS eligible clinicians would select the measures most relevant to their practice and that in most cases, the measures they select would meet the required case minimum. We plan to monitor measure selection trends under the performance category and will revise this policy if it appears MIPS eligible clinicians are reporting measures that are not relevant to their practice or measures that do not meet the required case minimum. In the resource use performance category, we believe MIPS eligible clinicians who are not attributed enough cases to be reliably measured should not be scored for the performance category. We have proposed to include many resource use measures that we believe are sufficiently developed and ready for evaluating resource use by MIPS eligible clinicians; however, if a MIPS eligible clinician is not attributed any (or very few) cases for the measure, then we do not believe the MIPS eligible clinician should be measured on performance.

We refer readers to section II.E.5.g.8. of this proposed rule for a detailed discussion of the scenarios in which a MIPS eligible clinician may not have sufficient measures applicable and available under the advancing care information performance category. For the CPIA performance category, however, we envision that all MIPS eligible clinicians would have sufficient activities applicable and available and do not propose any scenario where a MIPS eligible clinician would not receive a CPIA performance category score.

In addition to scenarios where a MIPS eligible clinician would have no scored measures for a performance category, we believe there may be scenarios in which a MIPS eligible clinician would have too few scored measures under the quality performance category for us to reliably calculate a performance category score that is worth half the weight of the CPS for the 2019 MIPS payment year. We propose that if a MIPS eligible clinician has fewer than three scored quality measures (either submitted measures or measures calculated from administrative claims data) for a performance period, we would consider the MIPS eligible clinician not to have a sufficient number of measures applicable and available for the 2019 MIPS payment year quality performance category weight and would therefore lower the weight of the quality performance category. In this situation, the MIPS eligible clinician has a quality performance category score, but has data for only one or two scored measures, which is not a sufficient number of measures for the quality performance category because the quality performance category would constitute half of the CPS for the 2019 MIPS payment year. In addition, as described in the next section, for MIPS eligible clinicians that are not scored on the resource use or advancing care information performance category, we propose to increase the weight of the quality performance category. For these reasons, we believe that for the first year of MIPS, the quality performance category requires a sufficient number of measures to justify its weight in the CPS. We will reconsider this policy in future years as the weights for the performance categories change. We may consider implementing a similar policy for the resource use performance category for future years, but not for the first year of MIPS based upon the lower weighting of the resource use performance category.

In section II.E.5.b., we are proposing for the quality performance category, generally, that MIPS eligible clinicians submit a minimum of six measures for scoring in MIPS. In addition, we propose to include up to three population-based measures derived from claims data. As described in section II.E.6.a.2., a MIPS eligible clinician may submit a measure that is not scored, either because the measure did not meet the required case minimum to be reliably measured or because fewer than 20 MIPS eligible clinicians with sufficient volume submitted a measure through a similar reporting mechanism and a benchmark could not be created for the performance or baseline period. We reiterate that a measure that is not scored due to not meeting the required case minimum or lack of a measure benchmark, is different than a required measure that is not reported. Any required measure that is not reported or reported with in a way that does not meet the data completeness requirements would receive a score of zero points and would be considered a scored measure.

We are concerned that if a large percentage of the expected measures are not able to be scored due to not meeting the required case minimums or a missing benchmark, then just one or two measures would contribute disproportionately to the CPS because the quality performance category score is worth 30 to 50 percent (depending on the year) of the CPS under section 1848(q)(5)(E)(i) of the Act. We do not believe a score for one or two quality measures can capture all the elements of quality performance during a performance period. We believe the lack of a sufficient number of measures for scoring limits the value of quality performance measurement toward the CPS. Therefore, we propose that if a MIPS eligible clinician has only two scored measures (including both submitted measures and measures derived from administrative claims data) to reduce the weight of the quality performance category by one-fifth (for example, from 50 percent to 40 percent in year 1) and redistribute the weight (for example, 10 percent in year 1) proportionately to the other performance categories for which the MIPS eligible clinician did receive a performance category score. If a MIPS eligible clinician has only one scored quality measure, then we propose to reduce the weight of the quality performance category by two-fifths (for example, from 50 percent to 30 percent in year 1) and redistribute the weight (for example, 20 percent in year 1) proportionately to the other performance categories for which the MIPS eligible clinician did receive a performance category score. Lowering the weight of the quality performance category would be consistent with the relatively low percentage of expected quality measures that are able to be scored.

We request comment on these proposals to identify MIPS eligible clinicians without sufficient measures and activities applicable and available and our proposals to reweight those performance categories. We also seek comment on alternative methods for reweighting performance categories for MIPS eligible clinicians without sufficient measures and activities in certain performance categories. We seek to ensure that reweighting would not cause an eligible clinician to be either advantaged or disadvantaged due to a lack of sufficient measures and activities applicable and available, and a corresponding inability to generate a score for a certain performance category.

(c) Redistributing Performance Category Weights

We propose at § 414.1380(c)(3) to reweight the performance categories for MIPS eligible clinicians when there are not sufficient measures and activities applicable and available to them. We propose to reweight the performance categories in the following situations.

If the MIPS eligible clinician does not receive a resource use or advancing care information performance category score, and has at least three scored measures (either submitted measures or those calculated from administrative claims) in the quality performance category, then we propose to reassign the weights of the performance categories without a score to the quality performance category. We believe this policy is appropriate for several reasons. First, section 1848(q)(5)(E)(i)(I)(bb) of the Act redistributes weight from the resource use performance category to the quality performance category in the first two years of MIPS. This proposal is consistent with that redistribution logic. In addition, MIPS eligible clinicians have experience reporting quality measures through the PQRS program and measurement in this performance category is more mature. Finally, for the 2019 MIPS payment year, quality performance would be worth at least half of the CPS. By requiring the MIPS eligible clinician to have at least three scored quality measures, we believe the quality performance category would be robust enough to support more weight reassigned to it than other performance categories. We may revisit this policy in future years as the weight for the resource use performance category increases and the weight for the quality performance category decreases.

We also propose an alternative that does not reassign all the weight to the quality performance category, but rather reassigns the weight proportionately to each of the other performance categories for which the MIPS eligible clinician has received a performance category score.

We request public comments on the proposal to reassign the weights to the quality performance category, as well as the alternate proposal to redistribute proportionately to other performance categories.

If the MIPS eligible clinicians have fewer than three scored measures in the quality performance category score, then we propose to reassign the weights for the performance categories without scores proportionately to the other performance categories for which the MIPS eligible clinician has received a performance category score. We request comment on this proposal.

Finally, because the CPS is a composite score, we believe the intention of section 1848(q)(5) of the Act is for MIPS eligible clinicians to be scored based on multiple performance categories. Basing a CPS on a single performance category, even a robust and familiar performance category like quality, would frustrate that intent. In our proposals, CPIA is the only performance category which would always have a performance category score. We are particularly concerned about the possibility that a MIPS eligible clinician might, for the reasons discussed above, not have sufficient measures applicable and available for the quality, resource use, and advancing care information performance categories, and would only receive a score for the CPIA performance category. The CPIA performance category is based on activities that are reported by attestation, not on measured performance. In addition, because CPIA is not as mature as the other performance categories, each of which include certain aspects of existing CMS programs, we are unsure how much variation we will have in the CPIA performance category. We do not think it would be equitable to allow MIPS eligible clinicians that attest to receive the maximum points for that performance category and then base the CPS solely on the CPIA performance category. Such a scenario may result in higher CPS and payment adjustment factors for some MIPS eligible clinicians based solely on the CPIA performance category, while other MIPS eligible clinicians are measured based on their performance under the other performance categories. Therefore, we propose that if a MIPS eligible clinician receives a score for only one performance category, we would assign the MIPS eligible clinician a CPS that is equal to the performance threshold described in section II.E.5., which means the eligible clinician would receive a MIPS adjustment factor of 0 percent for the year. We anticipate this proposal would affect very few MIPS eligible clinicians in year 1 and even fewer in future years as more eligible clinicians are able to report on and receive scores for more of the performance categories.

We welcome public comment on this proposal.

7. MIPS Payment Adjustments

a. Payment Adjustment Identifier and CPS Used in Payment Adjustment Calculation

i. Payment Adjustment Identifier

As we describe in section II.E.2 of this preamble, we propose to allow MIPS eligible clinicians to measure performance as an individual, as a group defined by TIN, or as an APM Entity group using the APM scoring standard, yet for purposes of the application of the MIPS adjustment factors to payments in accordance with section 1848(q)(6)(E) of the Act (referred to as the payment adjustment), we are proposing to use a single identifier, TIN/NPI, for all MIPS eligible clinicians, regardless of whether the TIN/NPI was measured as an individual, group or APM Entity group. In other words, a TIN/NPI may receive a CPS based on individual, group, or APM Entity group performance, but the payment adjustment would be applied at the TIN/NPI level.

We are proposing to use the single identifier, TIN/NPI, for the payment adjustment for a few reasons. First, the final eligibility status of some clinicians would not be known until after the performance period ends. For example, the calculations to determine which clinicians would be excluded from MIPS, such as identifying clinicians that are QPs or are below the low-volume threshold, occur after the performance period ends. Using TIN/NPI would allow us to correctly identify which TIN/NPIs are still MIPS eligible clinicians after the exclusion criteria have been applied.

Second, the identifiers for measurement are not mutually exclusive and using TIN/NPI to apply the payment adjustment would allow us to resolve any inconsistencies that arise from the measurement identifiers. For example, a TIN may have 40 percent of its eligible clinicians participating in a MIPS APM and the remaining 60 percent are not participating in any APM. The TIN elects to submit performance information for all the eligible clinicians in the TIN, including those that are participating in the MIPS APM, so that it can ensure all of its eligible clinicians are being measured in MIPS. We cannot simply use the APM

Entity and TIN identifiers because we either have eligible clinicians with duplicative data and overlapping scores, or we have portions of the measurement identifier carved out if we eliminate the overlap. In our example, the eligible clinicians participating in the MIPS APM would have data for two CPSs (one based on the APM Entity group performance and one based on the group TIN performance). The eligible clinicians not participating in the MIPS APM would have only one CPS (one based on the group TIN performance). Applying the payment adjustment at the TIN/NPI level provides us the flexibility to correctly identify and resolve the conflicts emerging when measurement identifiers overlap. The TIN/NPI identifier is mutually exclusive on all of our measurement identifier options; therefore, we believe this identifier can be consistently used for individual, group, or APM scoring standard identifiers. We refer readers to section II.E.2 for a discussion of identifiers and our proposals related to them.

ii. CPS Used in Payment Adjustment Calculation

Because we are proposing to use only TIN/NPI to apply the MIPS payment adjustments and because there is a gap between the performance period and the MIPS payment year, we believe we should assign the historical CPS to each TIN/NPI that is subject to MIPS for the payment year.

In general, we propose to use the CPS associated with the TIN/NPI combination in the performance period. For groups submitting data using the TIN identifier, we propose to apply the group CPS to all the TIN/NPI combinations that bill under that TIN during the performance period. For individual MIPS eligible clinicians submitting data using TIN/NPI, we propose to use the CPS associated with the TIN/NPI that is used during the performance period. For eligible clinicians in MIPS APMs, we propose to assign the APM Entity group's CPS to all the APM Entity Participant Identifiers that are associated with the APM Entity on December 31 of the performance period. We refer readers to section II.E.5.h for more information about the process to identify participating APM Entities. For eligible clinicians that participate in APMs for which the APM scoring standard does not apply, we propose to assign a CPS using either the individual or group data submission assignments described above.

In the case where a MIPS eligible clinician starts working in a new practice or otherwise establishes a new TIN that did not exist during the performance period, there would be no corresponding historical performance information or CPS for the new TIN/NPI. Because we want to connect actual performance to the individual MIPS eligible clinician as often as possible, in cases where there is no CPS associated with a TIN/NPI from the performance period, we propose to use the NPI's performance for the TIN(s) the NPI was billing under during the performance period. If the MIPS eligible clinician has only one CPS associated with the NPI from the performance period, then we propose to use that CPS. For example, if a MIPS eligible clinician worked in one practice (TIN A) in the performance period, but is working at a new practice (TIN B) during the payment year, then we would use the CPS for the old practice (TIN A/NPI) to apply the MIPS payment adjustment for the NPI in the new practice (TIN B/NPI). This proposal most closely links the MIPS eligible clinician's performance during the performance period to the payment adjustment. It also ensures that MIPS eligible clinicians who qualify for a positive payment adjustment are able to keep it, even if they change practices. For those who have a negative payment adjustment, this proposal also ensures MIPS eligible clinicians are still accountable for their performance.

In scenarios where the MIPS eligible clinician billed under more than one TIN during the performance period, and the MIPS eligible clinician starts working in a new practice or otherwise establishes a new TIN that did not exist during the performance period, we propose to use a weighted average CPS based on total allowed charges associated with the NPI from the performance period. This proposal would provide a CPS that is based on all the services the NPI billed to Medicare during the performance period. Table 26 presents an example of how this proposed approach would work. In this example, a MIPS eligible clinician (NPI) was assigned a CPS for two unique TIN/NPI combinations from the performance period (TIN A/NPI and TIN B/NPI). In the MIPS payment year, the eligible clinician is now billing for Medicare services under a third TIN/NPI combination without a previously calculated CPS (TIN C/NPI). In this case, the eligible clinician's MIPS adjustment for payments made to TIN C/NPI would be based on a weighted average of CPSs for TIN A/NPI and TIN B/NPI.

TABLE 26: Weighted Average CPS Example

Performance Category	Percent of Total Allowed Charges	Quality Performance Category Points	Resource Use Performance Category Points	CPIA Performance Category Points	Advancing Care Information Performance Category Points	CPS
TIN A/NPI	10%	27.5	5.0	10.0	25.0	67.5
TIN B/NPI	90%	21.0	8.0	10.0	19.5	58.5
TIN C/NPI (weighted average CPS)	0%	No score	No score	No score	No score	59.4*

*Weighted average = (67.5 x 10%) + (58.5 x 90%) = 59.4.

If an NPI did not have any allowed charges in the performance period, then the clinician would not be included in MIPS due to the low-volume exclusion.

We also propose an alternative proposal where in lieu of taking the weighted average, we take the highest CPS from the performance period, which would be a CPS of 67.5 in the above example which is the CPS for TIN A/NPI. We believe the alternative approach rewards eligible clinicians for their prior performance and may be easier to implement in year 1 of MIPS. Our concern with this approach is that the highest CPS may represent a relatively small portion of the eligible clinician's practice during the performance period.

We request comment on the proposal to use the CPSs associated with the TIN(s) the NPI was billing under during the performance period when the TIN/NPI does not have a CPS from the performance period. We also request comment on our proposal to use a weighted average, and the alternative proposal to select the highest CPS from the performance period.

We also considered, but are not proposing, a policy to have the performance follow the group (TIN) rather than the individual (NPI). In other words, the MIPS eligible clinician's performance would be based on the historical performance of the new TIN that the MIPS eligible clinician moved to after the performance period, even though the MIPS eligible clinician was not part of this group during the performance period. This policy is consistent with the policy for the VM and would create incentives for MIPS eligible clinicians to move to higher performing practices (77 FR 69308). We also believe this policy would provide a lower burden for practice administrators as all MIPS eligible clinicians in the TIN would have the same payment adjustment. On the other hand, having performance follow the TIN creates some challenges. We are concerned that MIPS eligible clinicians who earned a positive adjustment based on their performance during the performance period would not retain the positive adjustment if the new TIN had a lower CPS. Finally, we believe that having performance follow the TIN could create some unanticipated issues with budget neutrality if high-performing TINs expand. For all of these reasons, we are not proposing to have performance follow the TIN, but rather have performance follow the NPI; however, we seek comment on this option.

In some cases, a TIN/NPI could have more than one CPS associated with it from the performance period, if the eligible clinician submitted duplicative data sets. In this situation, the MIPS eligible clinician has not changed practices, rather for example, a MIPS eligible clinician has a CPS for an APM Entity and a CPS for a group TIN. If a MIPS eligible clinician has multiple CPSs, we propose a multi-pronged approach to select the CPS that would be used to determine the MIPS payment adjustment. First, we propose that if a MIPS eligible clinician is a participant in MIPS APM, then the APM Entity CPS would be used instead of any other CPS (such as a group TIN CPS or individual CPS). We propose that if a MIPS eligible clinician has more than one APM Entity CPS for the same TIN (by participating in multiple MIPS APMs), we would apply the highest APM Entity CPS to the eligible clinician. Second, if a MIPS eligible clinician reports as a group and as an individual, we would calculate a CPS for the group and individual identifier and use the highest CPS for the TIN/NPI. We request comment on this proposed approach.

b. MIPS Adjustment Factors

Section 1848(q)(6)(A) of the Act requires the Secretary to specify a MIPS adjustment factor for each MIPS eligible clinician for a year determined by comparing the CPS of the MIPS eligible clinician for such year to the performance threshold established under paragraph (D)(i) for such year, in a manner such that the adjustment factors specified for a year result in differential payments. Section 1848(q)(6)(A)(iii) of the Act provides that MIPS eligible clinicians with CPS at or above the performance threshold receive a zero or positive adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a CPS at the performance threshold and an adjustment factor of the applicable percent is assigned for a CPS of 100. Section 1848(q)(6)(A)(iv) of the Act provides that MIPS eligible clinicians with CPS below the performance threshold receive a negative payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a CPS at the performance threshold and an adjustment factor of the negative of the applicable percent is assigned for a CPS of 0; further, MIPS eligible clinicians with CPS that are equal to or greater than zero, but not greater than one-fourth of the performance threshold, receive a negative payment adjustment factor that is equal to the negative of the applicable percent.

Section 1848(q)(6)(B) of the Act defines the applicable percent for each year as follows: (i) For 2019, 4 percent; (ii) for 2020, 5 percent; (iii) for 2021, 7 percent; and (iv) for 2022 and subsequent years, 9 percent.

Section 1848(q)(6)(C) of the Act provides for an additional positive MIPS adjustment factor for exceptional performance, for each of the years 2019 through 2024, for each MIPS eligible clinician with a CPS for a year at or above the additional performance threshold under paragraph (D)(ii) for such year. The additional MIPS adjustment factor shall be in the form of a percent and determined in a manner such that eligible clinicians having higher CPS above the additional performance threshold receive higher additional MIPS adjustment factors.

c. Determining the Performance Thresholds

(1) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of the MIPS, the Secretary shall compute a performance threshold with respect to which the CPS of MIPS eligible clinicians are compared for purposes of determining the MIPS adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, which may be reassessed every three years) of the CPS for all MIPS eligible clinicians for a prior period specified by the Secretary. Section 1848(q)(6)(D)(iii) of the Act outlines a special rule for the initial two years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS adjustment factors under paragraph (A) and an additional performance threshold for purposes of determining the additional MIPS adjustment factors under paragraph (C), each of which shall be based on a period prior to the performance periods and take into account data available with respect to performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary.

We define the term performance threshold at § 414.1305, as the level of performance that is established for a performance period at the CPS level. CPSs above the performance threshold receive a positive MIPS adjustment factor and CPSs below the performance threshold receive a negative MIPS adjustment factor. CPSs that are equal to or greater than 0, but not greater than one-fourth of the performance threshold receive the maximum negative MIPS adjustment factor for the MIPS payment year. CPSs at the performance threshold receive a neutral MIPS adjustment factor.

To establish the performance threshold for the 2019 MIPS payment year, we propose to model 2014 and 2015 Part B allowed charges, 2014 and 2015 PQRS data submissions, 2014 and 2015 QRUR and sQRUR feedback data, and 2014 and 2015 Medicare and Medicaid EHR Incentive Program data to inform where the performance threshold should be. We would use this data to estimate the impact of the quality and resource use scoring proposals. We would also use the EHR Incentive Program information to estimate which MIPS eligible clinicians are likely to receive points for the advancing care information performance category. Because of the lack of historical data for the CPIA performance category, we would apply some sensitivity analyses to help inform where the performance threshold should be.

For the 2019 MIPS payment year, we propose to set the performance threshold at a level where approximately half of the eligible clinicians would be below the performance threshold and half would be above the performance threshold, which we believe is consistent with the intent of section 1848(q)(6)(D)(i) of the Act which requires the performance threshold in year 3 and beyond to be equal to the mean or median of CPS from a prior period. We also considered other policy options when setting the performance threshold. For example, we considered setting the performance threshold so that the scaling factor (which is described in section II.E.7.b) is 1.0. We could set the performance threshold based on policy goals to ensure a minimum number of points are earned before an eligible clinician is able to receive a positive adjustment factor and potentially an additional adjustment factor for exceptional performance. We seek comment on the policy options for setting the performance threshold.

We would determine the performance threshold in accordance with the methodology established in the final rule. We intend to publish the performance threshold on the CMS Web site prior to the performance period.

(2) Additional Performance Threshold for Exceptional Performance

In addition to the performance threshold, section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional positive MIPS adjustment factors for exceptional performance under paragraph (C). For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible CPS above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual CPS for MIPS eligible clinicians with CPS at or above the performance threshold with respect to the prior period described in section 1848(q)(6)(D)(i) of the Act.

We define at § 414.1305 the additional performance threshold as an additional level of performance, in addition to the performance threshold, for a performance period at the CPS level at or above which a MIPS eligible clinician may receive an additional positive MIPS adjustment factor. For each year of the MIPS, we will compute an additional performance threshold for purposes of determining the additional MIPS adjustment factors under section 1848(q)(6)(C) of the Act. We propose at § 414.1405(e) the following methods for computing the additional performance threshold: the threshold shall be equal to the 25th percentile of the range of possible CPS above the performance threshold; or it shall be equal to the 25th percentile of the actual CPS for MIPS eligible clinicians with CPS at or above the performance threshold with respect to the prior period used to determine the performance threshold.

As discussed above, section 1848(q)(6)(D)(iii) of the Act outlines a special rule for establishing the additional performance threshold for the initial two years of MIPS. Because 2019 is the first MIPS payment year, we do not have any actual CPS for MIPS eligible clinicians to use for purposes of defining an additional performance threshold under the methodology proposed above. Therefore, we propose to establish the additional performance threshold at the 25th percentile of the range of possible CPS above the performance threshold. For example, if the performance threshold is 60, then the range of possible CPS above the performance threshold would be 61–100. The 25th percentile of those possible values is 70. We intend to publish the exceptional performance threshold with the performance threshold prior to the performance period.

d. Scaling/Budget Neutrality

Section 1848(q)(6)(F)(i) of the Act provides, with respect to positive MIPS adjustment factors for eligible clinicians whose CPS is above the performance threshold under paragraph (D)(i) for such year, the Secretary shall increase or decrease such adjustment factors by a scaling factor (not to exceed 3.0) in order to ensure that the budget neutrality requirement of clause (ii) is met. Stated generally, budget neutrality as required by section 1848(q)(6)(F)(ii) of the Act means the estimated increase in the aggregate allowed charges resulting from the application of positive MIPS adjustment factors under paragraph (A) (after application of the scaling factor) is equal to the estimated decrease in the aggregate allowed charges resulting from the application of negative MIPS adjustment factors under paragraph (A). Under section 1848(q)(6)(F)(iii) of the Act, budget neutrality requirements shall not apply if all MIPS eligible clinicians receive CPS for a year that are below the performance threshold under paragraph (D)(i) for such year, or if the maximum scaling factor (3.0) is applied for a year.

e. Additional Adjustment Factors

Section 1848(q)(6)(C) of the Act requires, for each of the years 2019 through 2024, the Secretary to specify an additional positive MIPS adjustment factor for each MIPS eligible clinician whose CPS for a year is at or above the additional performance threshold established under paragraph (D)(ii) for that year. This additional adjustment factor is required to take the form of a percentage and to be determined by the Secretary such that MIPS eligible clinicians with higher CPS above the additional performance threshold receive higher additional MIPS adjustment factors. Section 1848(q)(6)(F)(iv)(I) of the Act provides, in specifying the additional adjustment factors under paragraph (C) for each applicable MIPS eligible clinician for a year, the Secretary shall ensure that the estimated aggregate increase in payments under Part B resulting from the application of such additional adjustment factors shall be equal to $500,000,000 for each year beginning with 2019 and ending with 2024. We refer to the $500,000,000 increase in payments as aggregate incentive payments. Section 1848(q)(6)(F)(iv)(II) of the Act provides that the additional adjustment factor for each applicable MIPS eligible clinician shall not exceed 10 percent, which may result in an aggregate increase in payments that is less than $500,000,000 as described in subclause (I).

To be consistent with the MIPS adjustment factors under section 1848(q)(6)(A) of the Act, we propose to apply a linear sliding scale where MIPS eligible clinicians with a CPS at the additional performance threshold would receive 0.5 percent additional adjustment factor and MIPS eligible clinicians with a CPS equal to 100 would receive a 10 percent maximum additional adjustment factor. Similar to the adjustment factor, we would apply a scaling factor that is greater than 0 and less than or equal to 1.0 if needed to ensure distribution of the $500,000,000 increase in payments. The scaling factor must be greater than 0 to ensure that MIPS eligible clinicians with higher CPS receive a higher additional adjustment factor. The scaling factor cannot exceed 1.0; the 10 percent maximum additional adjustment factor could only decrease and not increase because section 1848(q)(6)(F)(iv)(II) of the Act provides that the additional adjustment factor shall not exceed 10 percent. We are proposing the starting point for the additional adjustment factor at 0.5 percent for a CPS at the additional performance threshold because this would provide a large enough incentive for MIPS eligible clinicians to strive for the additional performance threshold, while still providing the opportunity for a positive slope on the linear sliding scale. If we are unable to achieve a linear sliding scale starting at 0.5 percent (because the estimated aggregate increase in payments for a year would exceed $500 million), then we propose to lower the starting percentage for a CPS at the additional performance threshold until we are able to create the linear sliding scale with a scaling factor greater than 0 and less than or equal to 1.0. A MIPS eligible clinician with a CPS that is below the additional performance threshold would not be eligible for an additional adjustment factor. We request comments on these proposals.

f. Application of the MIPS Adjustment Factors

Section 1848(q)(6)(E) of the Act provides that for items and services furnished by a MIPS eligible clinician during a year (beginning with 2019), the amount otherwise paid under Part B with respect to such items and services and MIPS eligible clinician for such year, shall be multiplied by 1 plus the sum of the MIPS adjustment factor determined under paragraph (A) divided by 100, and as applicable, the additional MIPS adjustment factor determined under paragraph (C) divided by 100. We would apply the adjustment factors in accordance with section 1848(q)(6)(E) of the Act.

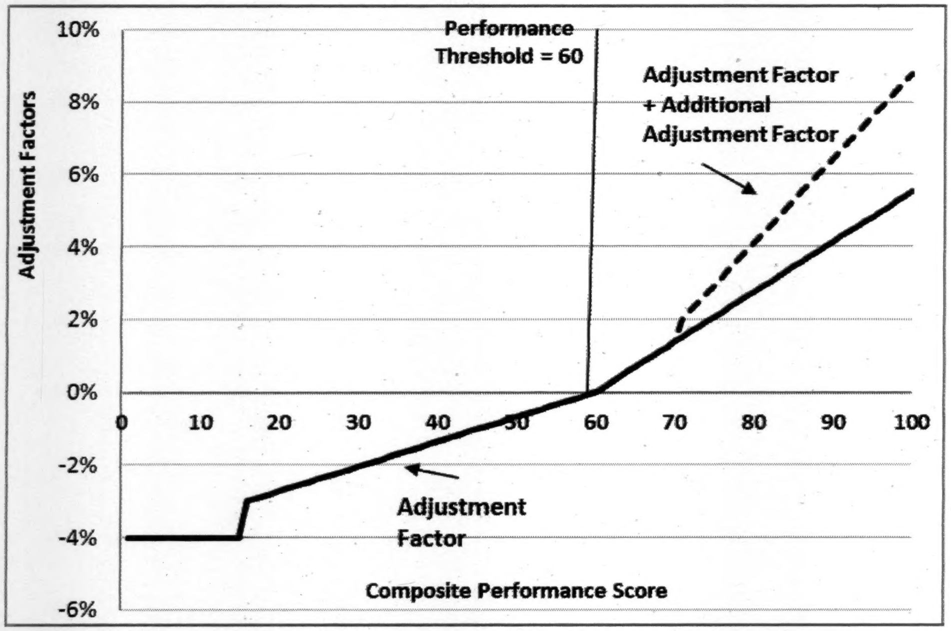
We request comment on our proposals.

g. Example of Adjustment Factors

Figure A provides an example of how various CPS would be converted to an adjustment factor and potentially an additional adjustment factor, using the statutory formula. In this example, the performance threshold is 60. The applicable percentage is 4 percent for 2019. The adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest negative applicable percentage (negative 4 percent for 2019), and 100 being the highest positive applicable percentage. However, there are two modifications to this linear sliding scale. First, there is an exception for a CPS between 0 and ¼ of the performance threshold (0–15 in our example). All MIPS eligible clinicians with a CPS in this range would receive the lowest negative applicable percentage (negative 4 percent for 2019). Second, the linear sliding scale line for the positive adjustment factor is adjusted by the scaling factor (which is determined by the formula described in section II.E.7.c.) If the scaling factor is greater than 0 and less than or equal to 1.0, then the adjustment factor for a CPS of 100 would be less than or equal to 4 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the adjustment factor for a CPS of 100 would be higher than 4 percent. Only those MIPS eligible clinicians with a CPS equal to 60 (which is the performance threshold in this example) would receive no adjustment. In Figure A, the scaling factor for the adjustment factor is 1.37. MIPS eligible clinicians with a CPS equal to 100 would have an adjustment of 5.5 percent (4.0 percent × 1.37).

For the performance threshold of 60, the additional performance threshold for exceptional performance is 70. A CPS of 70 would have an additional adjustment factor of 0.5 percent, and the amount of the additional adjustment factor would increase to 10 percent times a scaling factor that is greater than 0 and less than or equal to 1.0. In Figure A, the scaling factor for the additional adjustment factor is 0.32. Therefore, MIPS eligible clinicians with a CPS of 100 would have an additional adjustment of 3.2 percent (10 percent × 0.32). The total adjustment for a MIPS eligible clinician with a CPS equal to 100 would be 1 + 0.055 + 0.032 = 1.087, for a total positive adjustment of 8.7 percent.

FIGURE A: Illustrative Example of MIPS Adjustment Factors Based on Composite Performance Scores (CPS)



Note: The adjustment factor for CPS values above the performance threshold is illustrative. For MIPS eligible clinicians with a CPS of 100, the adjustment factor would be 4 percent times a scaling factor greater than 0 and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent.

The final MIPS payment adjustments would be determined by the distribution of CPS across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive adjustment. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would have negative adjustments and relatively fewer MIPS eligible clinicians receive positive adjustments.

We request comment on our proposals.

8. Review and Correction of MIPS Composite Performance Score

a. Feedback and Information To Improve Performance

Through the MIPS and APMs RFI, we solicited comment on various questions related to performance feedback under section 1848(q)(12) of the Act, such as what type of information should be contained in the performance feedback data, how often the feedback should be made available, and who should be able to access the data. Several commenters stated that it would be beneficial if the performance feedback under MIPS contained all the data that contributes to an EP's CPS and any MIPS adjustment. Further, several commenters suggested that performance feedback allow for interactive use of the data. Commenters supported frequent availability of such data and many noted that a minimum of quarterly feedback data would be preferred. Commenters also noted that access to PQRS Feedback Reports currently was a challenge and some suggested that the EPs should be able to control who can access the feedback reports.

(1) Performance Feedback

(a) MIPS Eligible Clinicians

Under section 1848(q)(12)(A)(i) of the Act, as added by section 101(c)(1) of the MACRA, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and resource use performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the CPIA and advancing care information performance categories.

Beginning July 1, 2017, we propose to include information on the quality and resource use performance categories in the performance feedback. Within these performance categories, we propose to use fields similar (that is, quality and resource use) to those currently available in the Quality and Resource Use Reports (QRURs). Since the QRURs already provide information on quality and resource use we believe this is a good starting point for the data fields to be included in the performance feedback. Additional information on the current QRURs can be found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html.*

The first performance feedback is due on July 1, 2017. As this is prior to us having received any MIPS data, we propose to initially provide feedback to MIPS eligible clinicians who are participating in MIPS using historical data set(s), as available and applicable. For example, these historical data set(s) could be a baseline report, using data based off performance that occurred in CY 2015 or CY 2016 for applicable and available quality and resource use data. In the event that 2017 is the first MIPS performance period (as proposed in section II.E.4. of this rule), we would not anticipate receiving the first set of data for MIPS until 2018 (as proposed in section II.E.5. of this rule). At a minimum for the first year, we propose to provide performance feedback on an annual basis since the first performance feedback, required on July 1, 2017 would be based on historic data set(s). As the program evolves, and we can operationally assess/analyze the MIPS data, we may consider in future years providing performance feedback on a more frequent basis, such as quarterly. Section 1848(q)(12)(A)(i) of the Act requires the performance feedback to be provided "timely" (such as quarterly), which is our goal as MIPS evolves. In addition, we seek comments on whether we should include first year measures in the performance feedback, meaning new measures that have been in use for less than 1 year, regardless of submission methods. The reasoning behind first-year measures potentially not being reported is we need to review the data from the measure before this data is incorporated into performance feedback, as we want to ensure the data we are providing in the performance feedback is useful and has usability for our stakeholders. We request comments on these proposals.

In future years and as the program evolves, we intend to seek comment on the template, including but not limited to the data fields, for performance feedback. While section 1848(q)(12)(A)(i) of the Act only requires us to provide performance feedback for the quality and resource use performance categories, we understand that the CPIA and advancing care information performance categories are important MIPS data. Commenters to the MIPS and APMs RFI noted that CMS should consult with stakeholders to ensure this performance feedback is useful before this data is provided to MIPS eligible clinicians. Therefore, we may consider including feedback on the performance categories of CPIA and advancing care information in future years. Further, before we consider adding CPIA and advancing care information data to the performance feedback we would like to engage in stakeholder outreach to understand what data fields might be helpful and usable to MIPS eligible clinicians. Regarding the MIPS CPS, this is something we are targeting to provide annually as part of the performance feedback as the program evolves. As technically feasible, we are also planning to provide data fields such as the CPS and each of the four performance categories in future performance feedback once MIPS data becomes available. In addition, we plan to explore the possibility of including the MIPS adjustment factor (and, as applicable, the additional MIPS adjustment factor) in future performance feedback. We seek comment on the frequency with which this performance feedback should be provided, considerations for including CPIA and advancing care information, and data fields that should be included in the performance feedback as this program evolves.

(b) APM Entities

We proposed in section II.E.5.h.(15) of this rule that MIPS eligible clinicians who participate in APM Entities would receive performance feedback, as technically feasible.

(2) Mechanisms

Under section 1848(q)(12)(A)(ii) of the Act, the Secretary may use one or more mechanisms to make performance feedback available, which may include use of a web-based portal or other mechanisms determined appropriate by the Secretary. For the quality performance category, described in section 1848(q)(2)(A)(i) of the Act, the feedback shall, to the extent an eligible clinician chooses to participate in a data registry for purposes of MIPS (including registries under sections 1848(k) and (m)) of the Act, be provided based on performance on quality measures reported through the use of such registries. With respect to any other performance category (that is, resource use, CPIA, or advancing care information), the Secretary shall encourage provision of feedback through qualified clinical data registries (QCDRs) as described in sections 1848(m)(3)(E) of the Act.

We understand that the PQRS and VM programs have employed various communication strategies to notify health care providers of the availability of their PQRS Feedback Reports and QRURs, respectively, through the CMS portal. However, many health care providers are still unaware of these reports and/or have difficulty accessing their reports in the portal. Further, we are aware that some health care providers perceive the current reports as complex and often difficult to understand; while others find the QRURs, and the drill down data included in them on the Medicare beneficiaries they serve, very useful. We are continuing to work with stakeholders to improve the usability of these reports. As we transition to MIPS, we are committed to ensuring that eligible clinicians are able to access their performance feedback, and that the data are easy to understand while providing information that will help drive quality improvement. We propose to initially make performance feedback available using a CMS designated system, such as a web-based portal; if technically feasible perhaps an interactive dashboard. As further discussed in section II.E.7.e. of this proposed rule, we also propose to leverage additional mechanisms such as health IT vendors, registries, and QCDRs to help disseminate data/information contained in the performance feedback to eligible clinicians, where applicable. At this time, we believe that these additional mechanisms will only be able to provide information on the quality performance category for MIPS in regard to performance feedback.

We plan to coordinate with third party intermediaries such as health IT vendors and QCDRs as MIPS evolves to enable additional feedback to be sent on the resource use, advancing care information and CPIA performance categories. We seek comment on this for future rulemaking.

Comments received through the MIPS and APMs RFI noted issues associated with access to the current Feedback Reports for PQRS. Specifically, comments were received noting issues with Enterprise Identity Management (EIDM) and access to the portal to view PQRS Feedback Reports. Commenters also noted the need for a mechanism to be put in place to notify EPs when their PQRS Feedback Report is available. We propose to use the information contained in the provider or supplier's Medicare enrollment records, and stored in the Provider Enrollment, Chain, and Ownership System (PECOS), as the system of records for eligible clinicians' contact information that should be used when the MIPS performance feedback is available. It is therefore critical that eligible clinicians ensure that their Medicare enrollment records (especially in regard to phone and email contact information) are updated, meaning current, on a consistent basis in PECOS. If more than one email address is listed, then the email address that should be used for communication should be designated. We also intend to provide education and outreach on how to access performance feedback. We seek comment on additional means that could be used to notify or contact MIPS eligible clinicians and groups when their performance feedback is available.

(3) Use of Data

Under section 1848(q)(12)(A)(iii) of the Act, for purposes of providing performance feedback, the Secretary may use data, for a MIPS eligible clinician, from periods prior to the current performance period and may use rolling periods in order to make illustrative calculations about the performance of such professional. We believe "illustrative calculations" means an interim, snap shot in time of performance, or perhaps a "dry-run" of the data including measure rates. This would provide an indication of how a MIPS eligible clinician might be performing, but would not be conclusive. Since MIPS will not likely have comparable data until year 3 of the program, these "illustrative calculations" could be based on historical data sets available to CMS until actual data for MIPS is available.

(4) Disclosure Exemption

As stated under section 1848(q)(12)(A)(iv) of the Act, feedback made available under section 1848(q)(12)(A) of the Act shall be exempt from disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(5) Receipt of Information

Section 1848(q)(12)(A)(v) of the Act, states that the Secretary may use the mechanisms established under section 1848(q)(12)(A)(ii) of the Act to receive information from professionals. This allows for expanded use of the feedback mechanism to not only provide feedback on performance to eligible clinicians, but to also receive information from professionals.

We intend to explore the possibility of adding this feature to the CMS designated system, such as a portal, in future years under MIPS. This feature could be a mechanism where eligible clinicians can send their feedback (that is, if they are experiencing issues accessing their data, technical questions about their data, etc.) to CMS. We appreciate that eligible clinicians may have questions regarding the information contained in their performance feedback. In order to assist eligible clinicians, we intend to establish resources, such as a helpdesk or offer technical assistance, to help address questions with the goal of linking these resource features to the CMS designated system, such as a portal.

Additionally, we seek comment on the types of information eligible clinicians would like to send to CMS via this mechanism.

(6) Additional Information—Type of Information

Section 1848(q)(12)(B)(i) of the Act, states that beginning July 1, 2018, the Secretary shall make available to MIPS eligible clinicians information about the items and services for which payment is made under Title 18 that are furnished to individuals who are patients of MIPS eligible clinicians by other suppliers and providers of services. This information may be made available through mechanisms determined appropriate by the Secretary, such as the proposed CMS designated system that would also provide performance feedback. Section 1848(q)(12)(B)(ii) of the Act specifies that the type of information provided may include the name of such providers, the types of items and services furnished, and the dates items and services were furnished. Historical data regarding the total, and components of, allowed charges (and other figures as determined appropriate by the Secretary) may also be provided. We seek comment on the type of information MIPS eligible clinicians would find useful and the preferred mechanisms to provide such information, as well as, arrangements that should be in place regarding this data (that is, eligible clinicians sharing data). We also seek comment as to whether additional information regarding beneficiaries attributed to a MIPS eligible clinician under the resource use performance category or information about which MIPS eligible clinician(s) beneficiaries to whom a given MIPS eligible clinician provides services were attributed would be useful feedback in regards to quality improvement efforts.

(7) Performance Feedback Template

The performance feedback under section 1848(q)(12)(A) of the Act is meant to be meaningful and usable to eligible clinicians. In an effort to ensure these data are tailored to the needs of eligible clinicians, we solicited comment through the MIPS and APMs RFI and received numerous comments regarding overall format of the performance feedback template. Suggestions were made on what this feedback should include for MIPS. We intend to collaborate with stakeholders outside of notice-and-comment rulemaking on how the performance feedback should look for MIPS; as well as, what data elements would be useful for eligible clinicians. We seek comment on the fields that should be included in the performance feedback template for MIPS eligible clinicians.

b. Announcement of Result of Adjustments

Section 1848(q)(7) of the Act requires that under the MIPS, the Secretary shall, not later than 30 days prior to January 1 of the year involved, make available to MIPS eligible clinicians the MIPS adjustment factor (and, as applicable, the additional MIPS adjustment factor) applicable to the eligible clinician for items and services furnished by the professional for such year. The Secretary may include such information in the confidential feedback under section 1848(q)(12) of the Act.

If technically feasible, we propose to include the MIPS adjustment factor (and, as applicable, the additional MIPS adjustment factor) in the performance feedback for eligible clinicians provided under section 1848(q)(12)(A) of the Act. If it is not technically feasible to provide this information in the performance feedback, we propose to make it available through another mechanism as determined appropriate by the Secretary (such as a portal or a CMS designated Web site) and seek comment on mechanisms that might be appropriate. The first announcement will be available no later than December 1, 2018 to meet statutory requirements. We request comment on these proposals.

c. Targeted Review

Section 1848(q)(13)(A) of the Act requires the establishment of a process under which a MIPS eligible clinician may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to such MIPS eligible clinician for a year.

We recognize that a principled approach to requesting and conducting a targeted review is required under the MACRA in order to minimize burdens on MIPS eligible clinicians and ensure transparency under MIPS. We also believe it is important to retain the flexibility to modify MIPS eligible clinicians' CPS or payment adjustment based on the results of targeted review. This will lend confidence to the determination of the CPS and payment adjustments, as well as, providing finality for the MIPS eligible clinician after the targeted review is completed. It will also minimize the need for claims reprocessing. We are proposing an approach below that outlines the factors that we would use to determine if a targeted review may be conducted. In keeping with the statutory direction that this process be "informal," we have attempted to minimize the associated burden on the MIPS eligible clinician to the extent possible.

In accordance with section 1848(q)(13)(A) of the Act, we propose at § 414.1385 to adopt a targeted review process under MIPS wherein a MIPS eligible clinician may request that we review the calculation of the MIPS adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS adjustment factor under section 1848(q)(6)(C) of the Act applicable to such MIPS eligible clinician for a year. Because this review will be limited to the calculation of the MIPS adjustment factor and, as applicable, the additional MIPS adjustment factor, we anticipate we may find it necessary to review data related to the measures and activities and the calculation of the CPS according to the defined methodology. The following are examples of circumstances under which a MIPS eligible clinician may wish to request a targeted review. This is not a comprehensive list of circumstances:

- The MIPS eligible clinician believes that measures or activities submitted to CMS during the submission period and used in the calculations of the CPS and determination of the adjustment factors have calculation errors or data quality issues. These submissions could be with or without the assistance of a third party intermediary; or
- The MIPS eligible clinician believes that there are certain errors made by CMS, such as performance category scores were wrongly assigned to the MIPS eligible clinician (for example, the MIPS eligible clinician should have been subject to the low-volume threshold exclusion and should not have received a performance category score).

We believe that a fair targeted review request process requires accessibility to all MIPS eligible clinicians within a reasonable period of time and provides electronic and telephonic communication for questions regarding the targeted review process, as well as for the actual request for review and receipt of the decision on that request. The targeted review process will use the same help desk support mechanism as is provided for MIPS as a whole.

We further propose at § 414.1385 to adopt the following general process for targeted reviews under section 1848(q)(13)(A):

- A MIPS eligible clinician electing to request a targeted review may submit their request within 60 days (or a longer period specified by us) after the close of the data submission period. All requests for targeted review must be submitted by July 31 after the close of the data submission period or by a later date that we specify in guidance.
- We will provide a response with our decision on whether or not a targeted review is warranted. If a targeted review is warranted, the timeline for completing that review may be dependent on the number of reviews requested (for example, multiple reviews versus a single review by one MIPS eligible clinician) and general nature of the review.
- As this process is informal and the statute does not require a formal appeals process, we will not include a hearing process. The MIPS eligible clinician may submit additional information to assist in their targeted review at the time of request. If we or our contractors request additional information from the MIPS eligible clinician, the supporting information must be received from the MIPS eligible clinician by us or our contractors within 10 calendar days of the request. Non-responsiveness to the request for additional information will result in the closure of that targeted review request, although another review request may be submitted if the targeted review submission deadline has not passed.
- Since this is an informal review process and given the limitations on review under section 1848(q)(13)(B) of the Act, decisions based on the targeted review will be final, and there will be no further review or appeal.

If a request for targeted review is approved, the outcome of such review may vary. For example, we may determine that the clinician should have been excluded from MIPS, re-distribute the weights of certain performance categories within the CPS (for example, if a performance category should have been weighted at zero), or recalculate a performance category score in accordance with the scoring methodology for the affected category, if technically feasible.

We request comments on these proposals.

d. Review Limitation

Section 1848(q)(13)(B) of the Act, as added by section 101(c)(1) of the MACRA, provides there shall be no administrative or judicial review under sections 1869 and 1878 of the Act, or otherwise of the following:

- The methodology used to determine the amount of the MIPS adjustment factor and the amount of the additional MIPS adjustment factor and the determination of such amounts;
- The establishment of the performance standards and the performance period;
- The identification of measures and activities specified for a MIPS performance category and information made public or posted on our Physician Compare Web site; and
- The methodology developed that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

We propose at § 414.1385 to implement these provisions as written in the statute.

We would reject any requests for targeted review under section 1848(q)(13)(A) of the Act that focus on the areas precluded from review under section 1848(q)(13)(B) of the Act. We request comments on this proposal.

e. Data Validation and Auditing

Our experience with the PQRS, VM and Medicare EHR Incentive Programs, has demonstrated the value of data validation and auditing as an important part of program integrity, which is necessary to ensure valid, reliable data. The current voluntary data validation process for PQRS and the audit process for the Medicare EHR Incentive Program are multi-step processes. We communicate the types of data elements that may be included for data validation across multiple Web sites and our documents. This includes defining specific data that may be abstracted from the certified EHR technology, as well as other documented records.

As we begin the MIPS, our strategy is to combine our past program integrity processes of the data validation process used in PQRS, and the auditing process used in the Medicare EHR Incentive Program into one set of requirements for MIPS eligible clinicians and groups, which we refer to as "data validation and auditing." Based on our need for valid and reliable data on which to base a MIPS eligible clinician's or group's payment, we propose certain requirements for MIPS eligible clinicians and groups submitting data for the 2017 performance period (see section II.E.4) under MIPS. Further, we propose at § 414.1390 to selectively audit MIPS eligible clinicians on a yearly basis, and that if a MIPS eligible clinician or group is selected for audit, the MIPS eligible clinician or group would be required to do the following in accordance with applicable law:

- Comply with data sharing requests, providing all data as requested by us or our designated entity. All data must be shared with CMS or our designated entity within 10 business days or an alternate time frame that is agreed to by CMS and the MIPS eligible clinician or group. Data would be submitted via email, facsimile, or an electronic method via a secure Web site maintained by CMS.
- Provide substantive, primary source documents as requested. These documents may include: Copies of claims, medical records for applicable patients, or other resources used in the data calculations for MIPS measures, objectives and activities. Primary source documentation also may include verification of records for Medicare and

non-Medicare beneficiaries where applicable.

We propose that we would monitor MIPS eligible clinicians and groups on an ongoing basis for data validation, auditing, program integrity issues and instances of non-compliance with MIPS requirements. If a MIPS eligible clinician or group is found to have submitted inaccurate data for MIPS, we propose that we would reopen, revise, and recoup any resulting overpayments in accordance with the rules set forth at § 405.980 (re-opening rules), § 450.982 and § 450.984 (revising rules); and § 405.370 and § 405.373 (recoupment rules). It is important to note that at § 405.980(b)(3) there is an exception whereby we have the authority to re-open at any time for fraud or similar fault. If we re-open the initial determination we must revise it, and send out a notice of the revised determination under § 450.982. We also propose that we would recoup any payments from the MIPS eligible clinician by the amount of any debts owed to us by the MIPS eligible clinician and likewise, we would recoup any payments from the group by the amount of any debts owed to us by the group. We also note that we would need to limit each such data validation and audit request to the minimum data necessary to conduct validation.

We propose all MIPS eligible clinicians and groups that submit data to CMS electronically must attest to the accuracy and completeness to the best of their knowledge of any data submitted to us. This attestation will occur prior to any electronic data submissions, via a Web site maintained by CMS.

We request comments on these proposals.

9. Third Party Data Submission

One of our strategic goals in developing MIPS includes developing a program that is meaningful, understandable, and flexible for participating MIPS eligible clinicians. One way we believe this will be accomplished is through flexible reporting options to accommodate different practices and make measurement meaningful. We believe this goal can be accomplished by allowing MIPS eligible clinicians the flexibility of using third party intermediaries to collect or submit data on their behalf. Specifically, qualified registries, QCDRs, health IT vendors that obtain data from an eligible clinician's certified EHR technology, and CMS-approved survey vendors as discussed in the following proposed policies. In this section, we are specifying the requirements that must be met to become a third party intermediary.

In the PQRS program, quality measures data may be collected or submitted by third party vendors on behalf of an individual EP or group by: (1) A registry; (2) a QCDR; or (3) an EHR vendor that obtains data from an EP's certified EHR technology; or (4) a CMS-approved survey vendor. We propose at § 414.1400(a)(1) that MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by: (1) A qualified registry; (2) a QCDR; (3) a health IT vendor; or (4) a CMS-approved survey vendor. Furthermore, we propose at § 414.1400(a)(3) that third party intermediaries must meet all the requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary. As proposed at § 414.1400(a)(3)(ii), all submitted data must be submitted in the form and manner specified by CMS.

In the MIPS and APMs RFI, we solicited feedback on how we should address data integrity, testing and standards, and review and qualification processes for QCDRs. Subsequently, we also met with several organizations that were either a QCDR or are in the process of becoming a QCDR. Commenters agreed that data quality is a critical issue for QCDRs. To address some of the data quality concerns, some commenters suggested having processes in place in advance of reporting that could mitigate data errors. For example, this could include a process to reconcile TIN and NPI combinations. Several commenters also suggested limiting submission mechanisms to one submission mechanism per performance category to the extent possible. Commenters generally agreed that QCDRs should be required to submit data using uniform submission standards, with several suggesting the use of the Quality Reporting Document Architecture (QRDA) standard, which certified EHR technology is required to support.

Most commenters noted that uniform standards would ease participation by MIPS eligible clinicians and reduce barriers to entry. Others noted that we should work with ONC and the standards development organization Health Level Seven (HL7) to improve the QRDA standard for current submissions, and that in the future, we should prepare to support emerging standards such as Fast Healthcare Interoperability Resources. Commenters also noted that use of QRDA will align CMS requirements and ONC certification requirements as ONC's 2015 Edition Certification requires that all health information technology (IT) modules used for the submission of CQM data must at least be certified to the QRDA standard. Requiring QCDRs to use QRDA could help reduce vendor interface costs for MIPS eligible clinicians already using certified EHR technology and who desire to participate in registry reporting. Commenters also directed our attention towards the 2015 Edition Certification for additional information on improved test methods and to address historic issues and inaccuracies observed with past calculation and reporting of quality and performance data. With regard to testing, commenters were divided about whether we should require QCDR-specific testing. Several noted that certified EHR technology that support QCDRs have been tested already and that onerous testing may discourage participation. Commenters in favor of testing recommended a degree of flexibility in the early years of the program. Suggestions for testing included the use of comprehensive specifications and accurate testing tools far enough in advance of the performance period to allow developers and implementers to conduct robust testing. These specifications could be included in an Implementation Guide. Opportunities for early testing, using sample data was also emphasized. Commenters did express concern on the amount of time needed for troubleshooting and fixing errors early enough in the testing process such as format, content, and measure accuracy. Commenters suggested several ways we might implement testing, recommending that we:

- Test the accuracy, completeness, and reliability of measure calculations for specific, individual measures.
- Test the feasibility of data collection requirements.
- Pilot new CQMs before release; establish a regular schedule of CQM revisions, and ensure adequate time is allowed for implementation of the revisions.
- Align the ONC Health IT Certification program and CMS testing requirements for data submission.
- Expand the test data sets used by the Cypress Testing Tool. More information on the Cypress Testing Tool is available at: *http://projectcypress.org/about.html*.

There was a strong consensus that MIPS eligible clinicians should not be penalized for signing up with an entity that purported to offer reliable services but then was unable to accurately submit data to us. Several commenters suggested that entities that do not meet standards move to a probationary phase and eventually be prohibited from periods of future participation until standards are met. However, commenters also cautioned us not to move too quickly in moving entities to a probationary phase because many QCDRs are run by medical specialty societies and if they were to be disqualified to the detriment of physicians participating, it would also diminish physician enthusiasm for future submission of data.

Commenters had mixed responses regarding how to resolve inaccurate data submission problems when time did not allow for continued review. Commenters felt we should use a "trust but validate" methodology, allowing the QCDR to recalculate the performance rate or authorizing us to do so, but also that we should have validation processes in place as well once the recalculation of the performance rate occurs. Ultimately, we would need to be able to calculate all rates based on a submitted numerator and denominator. Commenters suggested that MIPS eligible clinicians should be assessed an average score or a "pass" for the MIPS quality performance category if data problems cannot be resolved in a timely manner or at the least not be penalized due to data errors outside their control. One commenter suggested use of a Data Quality Management (DQM) program for MIPS eligible clinicians that includes early data qualification evaluation processes to take advantage of feedback and assessments with thresholds for acceptance of data. MIPS eligible clinicians who demonstrate effort toward achieving high quality data submissions but were not able to meet the threshold should be chaperoned to that target and provided with guidance.

Commenters were also divided about our review and qualification of QCDRs to ensure our form and manner requirements are met. Several commenters were concerned with a CMS process in addition to an ONC certification process and recommended we work with ONC to align their certification to address our requirements for QCDRs. Commenters suggested that we also develop more robust implementation guides, and enhance our submission engine validation tool (SEVT).

a. Qualified Clinical Data Registries (QCDRs)

Section 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs under section 1848(m)(3)(E) of the Act in carrying out MIPS. Section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary, under the CPS methodology, to encourage MIPS eligible clinicians to report on applicable measures with respect to the quality performance category through the use of certified EHR technology and QCDRs. Section 1848(q)(2)(B)(iii)(II) of the Act requires that the CPIA subcategories specified by the Secretary include population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR. Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs.

Section 1848(m)(3)(E)(i) of the Act requires the Secretary to establish requirements for an entity to be considered a QCDR, which must include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out section 1848(m) of the Act. Section 1848(m)(3)(E)(iv) of the Act requires the Secretary to consult with interested parties in carrying out section 1848(m)(3)(E) of the Act.

Currently, the QCDR reporting mechanism provides a method to satisfy PQRS requirements based on satisfactory participation. We propose that entities interested in becoming a QCDR for MIPS go through a qualification process. This includes the QCDR meeting the definition of a QCDR, self-nomination requirements, and the requirements of a QCDR, including the deadlines listed below. This qualification process allows us to ensure that the entity has the capability to successfully report MIPS eligible clinicians' data to us and allows for review and approval of the QCDR's proposed non-MIPS quality measures. We intend to compile and post a list of entities that we "qualify" to submit data to us as a QCDR for purposes of MIPS on a Web site maintained by CMS.

Section 1848(q)(1)(E) of the Act encourages the use of QCDRs in carrying out the MIPS. Although section 1848(q)(5)(B)(ii)(I) of the Act specifically requires the Secretary to encourage MIPS eligible clinicians to use QCDRs to report on applicable measures with respect to the quality performance category and section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs, the statute does not specifically address usage of QCDRs for the other MIPS performance categories. Although we could limit the usage of QCDRs to assessing the quality performance category under MIPS and providing performance feedback, we believe it would be less burdensome for MIPS eligible clinicians if we expand the QCDRs capabilities. By allowing QCDRs to report on the quality, advancing care information, and CPIA performance categories we would alleviate the need for individual MIPS eligible clinicians and groups to use a separate mechanism to report data for these performance categories. It is important to note that no data will need to be reported for the resource use performance category since these measures are administrative claims-based. Therefore, we are proposing at § 414.1400(a)(2) to expand QCDRs' capabilities by allowing QCDRs to submit data on measures, activities, or objectives for any of the following MIPS performance categories:

(i) Quality;
(ii) CPIA; or
(iii) Advancing care information, if the MIPS eligible clinician or group is using certified EHR technology.

We believe this approach would permit a single QCDR to report on the quality, advancing care information, and CPIA performance category requirements for MIPS and should mitigate the risks, costs, and burden of MIPS eligible clinicians having to report multiple times to meet the requirements of MIPS.

We propose to define a QCDR at § 414.1305 as a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Examples of the types of entities that may qualify as QCDRs include, but are not limited to, regional collaboratives and specialty societies using a commercially available software platform, as appropriate.

(1) Establishment of an Entity Seeking To Qualify as a QCDR

We propose at § 414.1400(c) the establishment of a QCDR entity is required as follows: for an entity to become qualified for a given performance period as a QCDR, the entity must be in existence as of January 1 of the performance period for which the entity seeks to become a QCDR (for example, January 1, 2017, to be eligible to participate for purposes of performance periods beginning in 2017). The QCDR must have at least 25 participants by January 1 of the performance period. These participants do not need to be using the QCDR to report MIPS data to us; rather, they need to be submitting data to the QCDR for quality improvement.

(2) Self-Nomination Period

For the 2017 performance period we propose at § 414.1400(b) a self-nomination period from November 15, 2016 until January 15, 2017. For future years of the program, starting with the 2018 performance period, we propose to establish the self-nomination period from September 1 of the prior year until November 1 of the prior year. Entities that desire to qualify as a QCDR for the purposes of MIPS for a given performance period would need to self-nominate for that year and provide all information requested by CMS at the time of self-nomination. Having qualified as a QCDR in a prior year does not automatically qualify the entity to participate in MIPS as a QCDR in subsequent performance periods. For example, a QCDR may choose not to continue participation in the program in future years, or the QCDR may be precluded from participation in a future year due to multiple data or submission errors as noted below. Finally, QCDRs may want to update or change the measures or services or performance categories they intend to provide. As such, CMS believes an annual self-nomination process is the best process to ensure accurate information is conveyed to MIPS eligible clinicians and accurate data is submitted to MIPS.

We propose to require other information (described below) of QCDRs at the time of self-nomination. If an entity becomes qualified as a QCDR, they will need to sign a statement confirming this information is correct prior to listing it on their Web site. Once we post the QCDR on our Web site, including the services offered by the QCDR, we will require the QCDR to support these services/measures for its clients as a condition of the entity's qualification as a QCDR for purposes of MIPS. Failure to do so will preclude the QCDR from participation in MIPS in the subsequent year.

(3) Information Required at the Time of Self-Nomination

We propose that a QCDR must provide the following information to us at the time of self-nomination to ensure that QCDR data is valid:

- Organization Name (Specify Sponsoring Organization name and software vendor name if the two are different. For example, a specialty society in collaboration with a software vendor).
- MIPS performance categories (that is, categories for which the entity is self-nominating. For example, quality, advancing care information, and/or CPIA).
- Performance Period.
- Vendor Type (for example, qualified clinical data registry).
- Provide the method(s) by which the entity obtains data from its customers for each performance category for which it is approved: Claims, web-based tool, practice management system, certified EHR technology, other (please explain). If a combination of methods (Claims, web-based tool, Practice Management System, certified EHR technology, and/or other) is utilized, the entity should state which method(s) it utilizes to collect data (for example, performance numerator and denominator).
- Indicate the method the entity will use to verify the accuracy of each TIN/NPI it is intending to submit (for example, National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation).
- Describe the method that the entity will use to accurately calculate performance rates for quality measures based on the appropriate measure type and specification. For composite measures or measures with multiple performance rates, the entity must provide us with the methodology the entity uses to calculate these composite measures and measures with multiple performance rates. The entity should be able to report to us a calculated composite measure rate if applicable.
- Describe the method that the entity will use to accurately calculate performance data for CPIA and advancing care information based on the appropriate parameters or activities.
- Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to us (for all performance categories the QCDR is submitting data on, that is, quality, CPIA, and advancing care information, as applicable). Periodic examinations may be completed to compare patient record data with submitted data and/or ensure MIPS quality measures or other performance category (CPIA, advancing care information) activities were accurately reported and performance calculated based on the appropriate measure specifications (that is, accuracy of numerator, denominator, and exclusion criteria) or performance category requirements.
- Provide information on the entity's process for data validation for both individual MIPS eligible clinicians and groups within a data validation plan. For example, for individuals it is encouraged that 3 percent of the TIN/NPIs submitted to us by the QCDR be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Provide the results of the executed data validation plan by May 31 of the year following the performance period. If the results indicate the QCDR's validation reveals inaccuracy or low compliance provide to CMS an improvement plan. Failure to implement improvements may result in the QCDR being placed in a probationary status or disqualification from future participation.
- For non-MIPS quality measures, if the measure is risk-adjusted, the QCDR is required to provide details to CMS on their risk adjustment methodology (risk adjustment variables, and applicable calculation formula) at the time of the QCDR's self-nomination. The QCDR must submit the risk adjusted results to CMS when submitting a risk-adjusted measure on behalf of the QCDR's MIPS eligible clinicians for the performance period.

(4) QCDR Requirements for Data Submission

In addition, we propose that a QCDR must perform the following functions:

- For measures under the quality performance category and as proposed at § 414.1400(a)(4)(i), if the data is derived from certified EHR technology, the QCDR must be able to indicate this data source.
- QCDRs must provide complete quality measure specifications including data elements to us for non-MIPS quality measures intended for reporting from certified EHR technology.
- QCDRs must provide a plan to risk adjust (if appropriate for the measure) the non-MIPS quality measures data for which it collects and intends to transmit to us and must submit the risk-adjusted results (not the non-risk adjusted rates), to CMS. The risk adjustment methodology (formula and variables) must be integrated with the complete quality measure specifications. Specifically, for risk-adjusted non-MIPS quality measures, a QCDR is required to provide details to CMS on their risk adjustment methodology. The data elements used for risk adjustment may vary by measure and measure type. The risk adjustment methodology, including the risk adjustment variables, must be posted along with the measure's specifications on the QCDR's Web site. CMS believes risk-adjustment for certain outcomes measures is important to account for the differences in the complexities of care provided to

different patients. That is, some patients may have additional comorbidities which could affect their response to treatment and subsequently their outcome. Risk adjustment will help offset potential poorer outcomes for those MIPS eligible clinicians caring for sicker patients.

- QCDRs submitting MIPS quality measures that are risk-adjusted (and have the risk-adjusted variables and methodology listed in the measure specifications) must submit the risk-adjusted measure results to CMS when submitting the data for these measures.
- Submit quality, advancing care information, or CPIA data and results to us in the applicable MIPS performance categories for which the QCDR is providing data.
- A QCDR must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures. That is, we expect that the non-MIPS measures and their data elements (that is, specifications) comprising these measures be listed on the QCDR's Web site unless the measure is a MIPS measure, in which case the specifications will be posted by us.
- Submit to us data on measures, activities, and objectives for all patients, not just Medicare patients.
- Provide timely feedback, at least 6 times a year, on all of the MIPS performance categories that the QCDR will report to us. That is, if the QCDR will be reporting on data for the CPIA, advancing care information, or quality performance category, all results as of the feedback report date should be included in the information sent back to the MIPS eligible clinician. The feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the QCDR reports. The QCDR is only required to provide feedback based on the MIPS eligible clinician's data that is available at the time the feedback report is generated.
- Possess benchmarking capacity (for non-MIPS quality measures) that compares the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For non-MIPS measures the QCDR must provide us, if available, data from years prior (for example, 2015 data for the 2017 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide us, if available, with the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their Web site prior to the start of the performance period, to the extent permitted by applicable privacy laws.
- QCDRs must comply with any request by us to review the data submitted by the QCDR for purposes of MIPS in accordance with applicable law. Specifically, data requested would be limited to the minimum necessary for us to carry out, for example, health care operations or health oversight activities.
- Mandatory participation in ongoing support conference calls hosted by us (approximately one call per month), including an in-person QCDR kick-off meeting (if held) at our headquarters in Baltimore, MD. More than one unexcused absence could result in the QCDR being precluded from participation in the program for that year. If a QCDR is precluded from participation in MIPS, the individual MIPS eligible clinician or group would need to find another QCDR or utilize another data submission mechanism to submit their MIPS data.
- Agree that data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent of the total number of MIPS eligible clinicians submitted by the QCDR may result in notations on our qualified QCDR posting of low data quality and would place the QCDR on probation (if they decide to self-nominate for the next program year). If the QCDR does not reduce their data error rate below 3 percent in the subsequent year, they would continue to be on probation and have their listing on the CMS Web site continue to note the poor quality of the data they are submitting for MIPS. Data errors affecting in excess of 5 percent of the MIPS eligible clinicians submitted by the QCDR may lead to the disqualification of the QCDR from participation in the following year's program. As we gain additional experience with QCDRs, we intend to revisit and enhance these thresholds in future years.
- Be able to submit results for at least six quality measures including one cross-cutting measure and one outcome measure. If an outcome measure is not available, be able to submit results for at least one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures). If no outcome measure is available, then the QCDR must provide a justification for not including an outcome measure.
- QCDRs may request to report on up to 30 quality measures not in the annual list of MIPS quality measures. Full specifications will need to be provided to us at the time of self-nomination. CMS will review the quality measures and determine if they are appropriate for QCDR reporting.
- Enter into and maintain with its participating clinicians an appropriate Business Associate agreement that provides for the QCDR's receipt of patient-specific data from an individual MIPS eligible clinician or group, as well as the QCDR's disclosure of quality measure results and numerator and denominator data and/or patient specific data on Medicare and non-Medicare beneficiaries on behalf of MIPS eligible clinicians and groups.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the QCDR, has authorized the QCDR to submit quality measure results, CPIA measure and activity results, advancing care information objective results and numerator and denominator data and/or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation. This documentation must be obtained at the time the MIPS eligible clinician or group signs up with the QCDR to submit MIPS data to the QCDR and must meet the requirements of any applicable laws, regulations, and contractual business associate agreements. Groups participating in MIPS via a QCDR may have their group's duly authorized representative grant permission to the QCDR to submit their data to us. If submitting as a group, each individual MIPS eligible clinician does not need to grant their individual permission to the QCDR to submit their data to us.
- Not be owned and managed by an individual locally owned single specialty group (for example, single specialty practices with only one practice location or solo practitioner practices are prohibited from self-nominating to become a qualified QCDR).
- Be able to separate out and report on all payers including Medicare Part B FFS patients and non-Medicare patients.
- Provide the measure numbers for the MIPS quality measures on which the QCDR is reporting.
- Provide the measure title for the MIPS quality measures and CPIAs (if applicable) on which the QCDR is reporting.
- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (performance numerator).

- Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.
- Comply with a CMS-specified secure method for data submission, such as submitting the QCDR's data in an XML file.
- Sign a document verifying the QCDR's name, contact information, cost for MIPS eligible clinicians or groups to use the QCDR, services provided, and the measures and specialty-specific measure sets the QCDR intends to report. Once posted, on the QCDR's or CMS Web site, the QCDR will need to support the measures/measure sets confirmed by the QCDR. Failure to do so will preclude the QCDR from participation in MIPS in the subsequent year.
- Must provide attestation statements during the data submission period that all of the data (quality measures, CPIAs, and advancing care information measures and objectives, if applicable) and results are accurate and complete.
- For purposes of distributing feedback reports to MIPS eligible clinicians, collect a MIPS eligible clinician's email addresses and have documentation from the MIPS eligible clinician authorizing the release of his or her email address.
- Be able to calculate and submit measure-level reporting rates or, upon request, the data elements needed to calculate the reporting and performance rates by TIN/NPI and/or TIN.
- Be able to calculate and submit, by TIN/NPI and/or TIN, a performance rate (that is the percentage of a defined population who receive a particular process of care or achieves a particular outcome based on a calculation of the measures' numerator and denominator specifications) for each measure on which the TIN/NPI and/or TIN reports or, upon request the Medicare beneficiary data elements needed to calculate the performance rates.
- Provide the performance period start date the QCDR will cover.
- Provide the performance period end date the QCDR will cover.
- Report the number of reported instances, performance not met, meaning the quality actions was not performed for no valid reason as defined by the measure specification.
- For data validation purposes, provide information on the entity's sampling methodology. For example, it is encouraged that 3 percent of the MIPS eligible clinicians be sampled with a minimum sample of 10 MIPS eligible clinicians or a maximum sample of 50 MIPS eligible clinicians. For each MIPS eligible clinicians sampled, it is encouraged that 25 percent of the MIPS eligible clinicians' patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Submit all of the measures (MIPS measures and non-MIPS measures) including specifications for the non-MIPS measures to CMS on a designated Web page. The measures must address a gap in care. Outcome or other high priority types of measures are preferred. Simple documentation or "check box" measures are discouraged.

(5) QCDR Measure Specifications Requirements

A QCDR must provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS. We propose at § 414.1400(f) the QCDR must provide the following information:

- Provide descriptions and narrative specifications for, each measure activity, or objective for which it will submit to us by no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data. In future years, starting with the 2018 performance period, those specifications must be provided to us by no later than November 1 prior to the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data.
- For non-MIPS quality measures, the quality measure specifications must include: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. The narrative specifications provided must be similar to the narrative specifications we provide in our measures list. CMS will consider all non-MIPS measures submitted by the QCDR but the measures must address a gap in care and outcome or other high priority measures are preferred. Documentation or "check box" measures are discouraged. Measures that have very high performance rates already or address extremely rare gaps in care (thereby allowing for little or no quality distinction between MIPS eligible clinicians) are also unlikely to be approved for inclusion.
- For MIPS measures, the QCDR only needs to submit the MIPS measure numbers and/or the specialty-specific measure sets (if applicable).
- The QCDR must publicly post the measure specifications (no later than 15 days following our approval of these measure specifications) for each non-MIPS quality measure it intends to submit for MIPS. The QCDR may use any public format it prefers. Immediately following posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted. CMS will then post this information when it provides its list of QCDRs for the year.

(6) Identifying Non-MIPS Quality Measures

To clarify the definition of a non-MIPS quality measures for purposes of QCDRs submitting data for the MIPS quality performance category, we propose at § 414.1400(e) to consider the following types of quality measures to be non-MIPS quality measures:

- A measure that is not contained in the annual list of MIPS quality measures for the applicable performance period.
- A measure that may be in the annual list of MIPS quality measures but has substantive differences in the manner it is submitted by the QCDR. For example, if a MIPS quality measure is only reportable via the CMS Web Interface and a QCDR wishes to report this quality measure on behalf of its MIPS eligible clinicians, the quality measure would be considered a non-MIPS quality measure. This is because we would have only extracted the data collected from this quality measure using the CMS Web Interface, in which we utilize a claims-based assignment and sampling methodology to inform the groups on which patients they are to report, and the reporting of this quality measure would require changes to the way that the quality measure is calculated and reported to us via a QCDR instead of through the CMS Web Interface. Therefore, due to the substantive changes needed to report this quality measure via a QCDR, this CMS Web Interface quality measure would be considered a non-MIPS quality measure. CMS would not be able to directly compare MIPS eligible clinicians submitting the quality measure using the CMS Web Interface to those submitting the quality measure using the QCDR. Thus, this would be considered a non-MIPS quality measure.
- In addition, the CAHPS for MIPS survey currently could be submitted only using a CMS-approved survey vendor. Although the CAHPS for MIPS survey is proposed for inclusion in the MIPS measure set, we consider the changes that will need to be made available for reporting by individual

MIPS eligible clinicians (and not as a part of a group) significant enough as to treat the CAHPS for MIPS survey as a non-MIPS quality measure for purposes of reporting the CAHPS for MIPS survey via a QCDR. To the extent that further clarification on the distinction between a MIPS and a non-MIPS measure is necessary, we will provide additional guidance on our Web site.

(7) Collaboration of Entities To Become a QCDR

In the CY 2016 PFS final rule (80 FR 71136 through 71138) we finalized our proposal to allow collaboration of entities to become a QCDR based on our experience with the qualifying entities wishing to become QCDRs for performance periods. We received feedback from organizations who expressed concern that the entity wishing to become a QCDR may not meet the requirements of a QCDR solely on its own. We believe this policy supporting entity collaboration should be continued under MIPS. Therefore, we are proposing at § 414.1400 that an entity that may not meet the requirements of a QCDR solely on its own but could do so in conjunction with another entity, would be eligible for qualification through collaboration with another entity.

We propose to allow that an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR provided the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR (for example, September 1, 2016, to be eligible to participate for purposes of the 2017 performance period). Entities that have a mere verbal, non-written agreement to work together to become a QCDR by September 1 the year prior to the year for which the entity seeks to become a QCDR would not fulfill this proposed requirement. We request comments on these proposals.

b. Health IT Vendors That Obtain Data From MIPS Eligible Clinician's Certified EHR Technology

Currently, EHR-based systems are required to be considered certified EHR technology for multiple CMS quality programs. The Office of the National Coordinator for Health Information Technology (ONC) certification process has established standards and other criteria for structured data that EHRs must use. We propose to maintain this standard and require EHR-based data submission (whether transmitted directly from the EHR or from a data intermediary) to be certified EHR technology to submit quality measures, advancing care information, and CPIA data for MIPS. In addition, we propose at § 414.1400(a)(4) that health IT vendors that obtain data from a MIPS eligible clinician's certified EHR technology, like other third party intermediaries, would have to meet all requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary. This includes submitting data in the form and manner specified by CMS as proposed at § 414.1400(a)(4)(ii). We anticipate that for the initial years of MIPS the form and manner requirements will be similar to what was used in the PQRS program however, at a minimum these will be modified to address the four performance categories under MIPS and MIPS data calculation needs. As we gain experience under MIPS we anticipate that these form and manner requirements may change in future years to ease reporting burden. Historical form and manner requirements under the PQRS program are available here: *https://www.qualitynet.org/imageserver/pqrs/registry2015/index.htm* or *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/QRDA_2016_CMS_IG.pdf.* In addition, health IT vendors must comply with our QRDA Implementation Guides if submitting data from a certified EHR technology, which we anticipate will be similar to the one noted above. We anticipate providing further subregulatory guidance that would identify the certified EHR technology data formats that providers must submit. In addition, we propose at § 414.1325(b)(2) and (c)(2) to allow individual MIPS eligible clinicians and groups to submit data using certified EHR technology for the quality, CPIA, or advancing care information performance categories.

Although section 1848(q)(5)(B)(ii)(I) of the Act specifically requires the Secretary to encourage MIPS eligible clinicians to report on applicable measures using EHR technology with respect to the quality performance category, the statute does not specifically address allowing a third party intermediary—such as a health IT vendor to submit on a MIPS eligible clinician's behalf for the other performance categories. Although we could limit the usage of health IT vendors assessing the quality performance category under MIPS, we believe it would be less burdensome for MIPS eligible clinicians if we expand the health IT vendors' capabilities. By allowing health IT vendors to report on the quality, advancing care information, and CPIA performance categories we would alleviate the need for individual MIPS eligible clinicians and groups to use a separate mechanism to report data for these performance categories. Our intention is to encourage health IT vendors to design systems to be able to accept new types of EHR data (for example, CPIA and advancing care information) from MIPS eligible clinicians and groups—this would be in addition to the quality measure data that we already can accept. Therefore, we are proposing at § 414.1400(a)(2) to expand health IT vendors' capabilities by allowing health IT vendors to submit data on measures, activities, or objectives for any of the following MIPS performance categories:

(i) Quality;
(ii) CPIA; or
(iii) Advancing care information.

As proposed at § 414.1400(a)(1), health IT vendors submitting data on behalf of a MIPS eligible clinician or group would be required to obtain data from the MIPS eligible clinician's certified EHR technology. We believe this approach would permit a single health IT vendor to report on quality, advancing care information, and CPIA performance category requirements for MIPS and should mitigate the risks, costs, and burden of MIPS eligible clinicians having to report multiple times to meet the requirements of MIPS.

Health IT Vendors Data Requirements

We further propose that health IT vendors must be able to do the following:

- For measures, activities, and objectives under the quality, advancing care information, and CPIA performance categories, and as proposed at § 414.1400(a)(4)(i); if the data is derived from certified EHR technology, the health IT vendor must be able to indicate this data source.
- Either transmit data from the certified EHR technology or through a data intermediary in the CMS-specified form and manner, or have the ability for the individual MIPS eligible clinician and group to be able to submit data directly from their certified EHR technology, in the CMS-specified form and manner.

For MIPS eligible clinicians who choose to electronically submit quality, advancing care information, and CPIA data extracted from their certified EHR technology to an intermediary, the intermediary would then submit the measure and activity data to CMS in a CMS-specified form and manner on the MIPS eligible clinician's behalf for the respective performance period. In addition to meeting the appropriate data submission criteria for the quality, advancing care information, and CPIA performance categories for the MIPS EHR submission mechanism, MIPS eligible clinicians who choose the EHR submission mechanism would be required to have certified EHR technology meeting the proposed definition at § 414.1305. We request comments on these proposals.

c. Qualified Registries

We propose to define a qualified registry at § 414.1305 as a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS. In addition, we are proposing at § 414.1400(a)(2) to expand a qualified registry's capabilities by allowing qualified registries to submit data on measures, activities, or objectives for any of the following MIPS performance categories:

(i) Quality;

(ii) CPIA; or

(iii) Advancing care information, if the MIPS eligible clinician or group is using certified EHR technology.

(1) Establishment of an Entity Seeking To Qualify as a Registry

We propose at § 414.1400(h) that in order for an entity to become qualified for a given performance period as a qualified registry, the entity must be in existence as of January 1 of the performance period for which the entity seeks to become a qualified registry (for example, January 1, 2017, to be eligible to participate for purposes of performance periods beginning in 2017). The qualified registry must have at least 25 participants by January 1 of the performance period. These participants do not necessarily need to be using the qualified registry to report MIPS data to us; rather, they need to be submitting data to the qualified registry for quality improvement. We also propose a qualified registry must provide attestation statements from the qualified registry/MIPS eligible clinicians during the data submission period that all of the data (quality measures, CPIAs, and advancing care information measures and objectives, if applicable) and results are accurate and complete.

(2) Self-Nomination Period

For the 2017 performance period, we propose at § 414.1400(g) a self-nomination period from November 15, 2016 until January 15, 2017. For future years of the program, starting with the 2018 performance period, we propose to establish the self-nomination period from September 1 of the prior year until November 1 of the year in which the qualified registry seeks to be qualified. Entities that desire to qualify as a qualified registry for purposes of MIPS for a given performance period would need to provide all requested information to CMS at the time of self-nomination and would need to self-nominate for that performance period. Having qualified as a qualified registry does not automatically qualify the entity to participate in subsequent MIPS performance periods. For example, a qualified registry may choose not to continue participation in the program in future years, OR the qualified registry may be precluded from participation in a future year, due to multiple data or submission errors as noted below. As such, CMS believes an annual self-nomination process is the best process to ensure accurate information is conveyed to MIPS eligible clinicians and accurate data is submitted to MIPS.

We propose to require further information (described below) of qualified registries at the time of self-nomination. If an entity becomes qualified as a qualified registry, they will need to sign a statement confirming this information is correct prior to us listing their qualifications on their Web site. Once we post the qualified registry on our Web site, including the services offered by the qualified registry, we will require the qualified registry to support these services/measures for its clients as a condition of the entity's qualification as a qualified registry for purposes of MIPS. Failure to do so will preclude the qualified registry from participation in MIPS in the subsequent performance year.

(3) Information Required at the Time of Self-Nomination

We propose that a qualified registry must provide the following information to us at the time of self-nomination:

- Organization Name (Specify Sponsoring Organization name and software vendor name if the two are different. For example, a specialty society in collaboration with a software vendor).
- MIPS performance categories (that is, categories for which the entity is self-nominating to report. For example, quality measures, advancing care information, and/or CPIA).
- Performance Period.
- Vendor Type (for example, qualified registry).
- Provide the method(s) by which the entity obtains data from its customers for each performance category for which it is approved: Claims; web-based tool; practice management system; certified EHR technology; other (please explain). If a combination of methods (Claims, web-based tool, Practice Management System, certified EHR technology, and/or other) is utilized, please state which method(s) the entity utilizes to collect data (performance numerator and denominator).
- Indicate the method the entity will use to verify the accuracy of each TIN/NPI and/or TIN it is intending to submit (for example; National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation).
- Describe the method the entity will use to accurately calculate performance rates for quality measures based on the appropriate measure type and specification. For composite measures or measures with multiple performance rates, the entity must provide us with the methodology the entity uses to calculate these composite measures and measures with multiple performance rates. The entity should be able to report to us a calculated composite measure rate, if applicable.
- Describe the method that the entity will use to accurately calculate performance data for CPIA and advancing care information performance categories based on the appropriate parameters or activities.
- Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to us (for all performance categories the qualified registry is submitting data on; that is, quality, CPIA, and advancing care information, as applicable). Periodic examinations may be completed to compare patient record data with submitted data and/or ensure MIPS quality measures or other performance category (CPIA and advancing care information) activities, measures, or objectives were accurately reported and performance calculated based on the appropriate measure specifications (that is, accuracy of numerator, denominator, and exclusion criteria) or performance category requirements.

- Provide information on the entity's process for data validation for both individual MIPS eligible clinicians and groups within a data validation plan. For example, for individuals, it is encouraged that 3 percent of the MIPS eligible clinicians submitted to CMS by the qualified registry be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 MIPS eligible clinicians. For each MIPS eligible clinician sampled, it is encouraged that 25 percent of the MIPS eligible clinicians' patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Provide the results of the executed data validation plan by May 31st of the year following the performance period. If the results indicate the qualified registry's validation reveals inaccuracy or low compliance provide to us an improvement plan. Failure to implement improvements may result in the qualified registry being placed in a probationary status or disqualification from future participation.

(4) Qualified Registry Requirements for Data Submission

Further, we propose that a qualified registry must perform the following functions:

- For measures, activities, and objectives under the quality, advancing care information, and CPIA performance categories and as proposed at § 414.1400(a)(4)(i); if the data is derived from certified EHR technology, the qualified registry must be able to indicate this data source.
- A qualified registry submitting MIPS quality measures that are risk-adjusted (and have the risk-adjusted variables and methodology listed in the measure specifications) must submit the risk-adjusted measure results to CMS when submitting the data for these measures.
- Submit to us, quality measures and activities data on all patients, not just Medicare patients.
- Submit quality measures, advancing care information, or CPIA performance categories data and results to us in the applicable MIPS performance categories for which the qualified registry is providing data.
- Provide timely feedback, at least 4 times a year, on all of the MIPS performance categories that the qualified registry will report to us. That is, if the qualified registry will be reporting on data for the CPIA, advancing care information, or quality performance category, all results as of the feedback report date should be included in the information sent to the MIPS eligible clinician. The feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the qualified registry reports. The qualified registry is only required to provide feedback based on the MIPS eligible clinician's data that is available at the time the feedback report is generated.
- A qualified registry must comply with any request by us to review the data submitted by the qualified registry for purposes of MIPS in accordance with applicable law. Specifically, data requested would be limited to the minimum necessary for us to carry out, for example, health care operations or health oversight activities.
- Mandatory participation in ongoing support conference calls hosted by us (approximately one call per month), including an in-person qualified registry kick-off meeting (if held) at our headquarters in Baltimore, MD. More than one unexcused absence could result in the qualified registry being precluded from participation in the program for that year. If a qualified registry is precluded from participation in MIPS, the individual MIPS eligible clinician or group would need to find another entity to submit their MIPS data.
- Agree that data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent of the total number of MIPS eligible clinicians submitted by the qualified registry may result in notations on our qualified registry posting of low data quality and would place the qualified registry on probation (if they decide to self-nominate for the next program year). If the qualified registry does not reduce their data error rate below 3 percent in the subsequent year, they would continue to be on probation and have their listing on the CMS Web site continue to note the poor quality of the data they are submitting for MIPS. Data errors affecting in excess of 5 percent of the MIPS eligible clinicians submitted by the qualified registry may lead to the disqualification of the qualified registry from participation in the following year's program. As we gain additional experience with qualified registries, we intend to revisit and enhance these thresholds in future years.
- Be able to report at least six quality measures including one cross-cutting measure and one outcome measure. If an outcome measure is not available, be able to report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures).
- Enter into and maintain with its participating clinicians an appropriate Business Associate agreement that provides for the qualified registry's receipt of patient-specific data from an individual MIPS eligible clinician or group, as well as the qualified registry's disclosure of quality measure results and numerator and denominator data and/or patient specific data on Medicare and non-Medicare beneficiaries on behalf of MIPS eligible clinicians or group.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the qualified registry, has authorized the qualified registry to submit quality measure results, CPIA measure and activity results, advancing care information objective results and numerator and denominator data and/or patient-specific data on Medicare and non-Medicare beneficiaries to us for the purpose of MIPS participation. This documentation must be obtained at the time the MIPS eligible clinician or group signs up with the qualified registry to submit MIPS data to the qualified registry and must meet any applicable laws, regulations, and contractual business associate agreements. Groups participating in MIPS via a qualified registry may have their group's duly authorized representative grant permission to the qualified registry to submit their data to us. If submitting as a group each individual MIPS eligible clinician does not need to grant their individual permission to the qualified registry to submit their data to us.
- Not be owned and managed by an individual locally-owned single specialty group (for example, single specialty practices with only one practice location or solo practitioner practices are prohibited from self-nominating to become a MIPS qualified registry).
- Be able to separate out and report on all payers, including Medicare Part B FFS patients and non-Medicare patients.
- Provide the measure numbers for the MIPS quality measures on which the qualified registry is reporting.
- Provide the measure title (and specialty-specific measure set title, if applicable) for the MIPS quality measures and CPIAs (if applicable) on which the qualified registry is reporting.
- Indicate if the qualified registry will be reporting the advancing care information component measures and objectives.

- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (performance numerator).
- Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.
- Comply with a CMS-specified secure method for data submission, such as submitting the qualified registry's data in an XML file.
- Sign a document verifying the qualified registry's name, contact information, cost for MIPS eligible clinicians or groups to use the qualified registry, services provided, and the specialty-specific measure sets the qualified registry intends to report. Once posted on the qualified registry's CMS Web site, the qualified registry will need to support the measures/measure sets confirmed by the qualified registry. Failure to do so will may preclude the qualified registry from participation in MIPS in the subsequent year.
- Must provide attestation statements during the data submission period that all of the data (quality measures, CPIAs, and advancing care information measures and objectives, if applicable) and results are accurate and complete.
- For purposes of distributing feedback reports to MIPS eligible clinicians, collect a MIPS eligible clinician's email address(es) and have documentation from the MIPS eligible clinician authorizing the release of his or her email address.
- Be able to calculate and submit measure-level reporting rates or, upon request, the data elements needed to calculate the reporting and performance rates by TIN/NPI and/or TIN.
- Be able to calculate and submit, by TIN/NPI and/or TIN, a performance rate (that is the percentage of a defined population who receive a particular process of care or achieves a particular outcome based on a calculation of the measures' numerator and denominator specifications) for each measure on which the TIN/NPI and/or TIN reports or, upon request the Medicare and non-Medicare level data elements needed to calculate the performance rates.
- Provide the performance period start date the qualified registry will cover.
- Provide the performance period end date the qualified registry will cover.
- Report the number of instances in which the applicable submission criteria were not met, for example, the quality measure was not reported and a performance exclusion did not apply.
- For data validation purposes, provide information on the entity's sampling methodology. For example, if is encouraged that 3 percent of the MIPS eligible clinicians be sampled with a minimum sample of 10 MIPS eligible clinicians or a maximum sample of 50 MIPS eligible clinicians. For each MIPS eligible clinician sampled, it is encouraged that 25 percent of the MIPS eligible clinicians' patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.

We request comments on these proposals.

d. CMS-Approved Survey Vendors

As discussed in the section II.E.5.b. we propose to allow groups to report CAHPS for MIPS survey measures. We propose the data collected on the CAHPS for MIPS survey measures would be transmitted to us via a CMS-approved survey vendor.

For purposes of MIPS, we propose to define a CMS-approved survey vendor at § 414.1305 as a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and transmit survey measures data to CMS. We propose at § 414.1400(i) that vendors are required to undergo the CMS approval process for each year in which the survey vendor seeks to transmit survey measures data to CMS. We anticipate retaining the same policies and procedures we currently follow for a CMS-approved survey vendor for PQRS and apply them to a MIPS CMS-approved survey vendor. We propose the following requirements for a CMS-approved survey vendor for the CAHPS for MIPS survey. A CMS-approved survey vendor for CAHPS for MIPS must:

(1) Comply with and complete the Vendor Participation Form—We anticipate retaining the same application process and Vendor Participation Form that was required for the CAHPS for PQRS survey. Please refer to *http://www.pqrscahps.org/en/participation-form/* for further details. Therefore, we are proposing at § 414.1400(i) that all CMS-approved survey vendor applications and materials will be due April 30 of the performance period. However, we do seek comments on whether the deadline for CMS-approved survey vendor applications and materials should be earlier, such as prior to the beginning of the performance period. In addition, we propose the following items will be required for your organization to be a CMS-approved survey vendor of the CAHPS for MIPS Survey:

- Meet all of the Minimum Survey Vendor Business Requirements at the time of the submission of the Vendor Participation Form; and
- Complete the Vendor Participation Form.

(2) Comply with the Minimum Survey Vendor Business Requirements—We anticipate retaining the same minimum survey business requirements that were required for the CAHPS for PQRS survey. Please refer to *http://www.pqrscahps.org/en/business-requirements/* for further details. We propose Applicant Organizations (survey vendor and subcontractors) must possess all required facilities and systems to implement the CAHPS for MIPS Survey. Subcontractors will be subject to the same requirements as the applicant vendor. Organizations that are approved to administer the CAHPS for MIPS Survey must conduct all their CAHPS for MIPS business operations within the United States. This requirement applies to all staff and subcontractors. In addition, we propose to request information regarding:

- Relevant organization and survey experience.
- Survey capability and capacity.
- Adherence to quality assurance guidelines and participation in quality assurance activities.
- Documentation requirements.
- Adhere to all protocols and specifications, and agree to participate in training sessions.

Specifically, to obtain our approval, we propose that survey vendors would be required to undergo training, meet our standards on how to administer the survey, and submit a quality assurance plan. We would provide the identified survey vendor with an appropriate sample frame of beneficiaries from each group that has contracted with the survey vendor and elected to participate in the CAHPS for MIPS survey. The survey vendor would also be required to administer the survey according to established protocols to ensure valid and reliable results. More information on quality assurance and protocols can be reviewed at *http://www.pqrscahps.org/en/quality-assurance-guidelines/*. CMS-approved survey vendors would be supplied with mail and telephone versions of the survey in electronic form, and text for beneficiary pre-notification and cover letters. CAHPS for MIPS surveys can be administered in English, Spanish, Cantonese, Mandarin, Korean, Russian and/or Vietnamese. Survey vendors would be required to use appropriate quality control, encryption, security and backup procedures to maintain survey response data. The data would then be securely sent back to us for scoring and/or validation in accordance with applicable law. To ensure that a survey vendor possesses the ability to transmit survey measures data for a particular performance period, we propose to require survey vendors to undergo this approval process for each year in which the survey vendor seeks to transmit survey measures data to us. We request comments on this proposal.

e. Probation and Disqualification of a Third Party Intermediary

We propose at § 414.1400(k) a process for placing third party intermediaries on probation and for disqualifying such entities for failure to meet certain standards established by CMS. Specifically, we propose that if at any time we determine that a third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) has not met all of the applicable requirements for qualification, we may place the third party intermediary on probation for the current performance period and/or the following performance period, as applicable.

In addition, we propose CMS requires a corrective action plan from the third party intermediary to address any deficiencies or issues and prevent them from recurring. We propose the corrective action plan must be received and accepted by CMS within 14 days of the CMS notification to the third party intermediary of the deficiencies or probation. Failure to comply with this would lead to disqualification from MIPS for the subsequent performance period.

We propose probation to mean that, for the applicable performance period, the third party intermediary would not be allowed to miss any meetings or deadlines and would need to submit a corrective action plan for remediation or correction of deficiencies identified that resulted in the probation.

In addition, we propose that if the third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, CMS would annotate on the CMS qualified posting that the third party intermediary furnished data of poor quality and would place the entity on probation for the subsequent MIPS performance period with the opportunity to go on probation for a year to correct their deficiencies.

Further, we propose if the third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary would continue to be on probation and have their listing on the CMS Web site continue to note the poor quality of the data they are submitting for MIPS for one additional performance year. After two years on probation, the third party intermediary would be disqualified for the subsequent performance year. Data errors affecting in excess of 5 percent of the MIPS eligible clinicians or groups submitted by the third party intermediary may lead to the disqualification of the third party intermediary from participation for the following performance period. In placing the third party intermediary on probation; we would notify the third party intermediary of the identified issues, at the time of discovery of such issues.

Finally, we propose if the third party intermediary does not submit an acceptable corrective action plan within 14 days of notification of the deficiencies and correct the deficiencies within 30 days or before the submission deadline—whichever is sooner, we may disqualify the third party intermediary from participating in MIPS for the current performance period and/or the following performance period, as applicable. We request comments on these proposals.

(f) Auditing of Third Party Intermediaries Submitting MIPS Data

We propose at § 414.1400(j) that any third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) must comply with certain auditing requirements as a condition of their qualification or approval to participate in MIPS as a third party intermediary. Specifically, we propose the entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information will include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email. Further, we propose the entity must retain all data submitted to CMS for MIPS for a minimum of 10 years. We request comments on this proposal.

10. Public Reporting on Physician Compare

This section contains the proposed approach for publicly reporting on Physician Compare for the MIPS, APM, and other information as required by the MACRA.

Physician Compare draws its operating authority from section 10331(a)(1) of the Affordable Care Act. As required, by January 1, 2011, we developed a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other EPs who participate in the PQRS under section 1848 of the Act. More information on Physician Compare can be accessed on the Physician Compare Initiative Web site at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

The first phase of Physician Compare was launched on December 30, 2010 (*http://www.medicare.gov/physiciancompare*). Since the initial launch, Physician Compare has been continually improved and more information has been added. Currently, Web site users can view information about approved Medicare professionals, such as name, Medicare primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare Assignment status, education, residency, and American Board of Medical Specialties (ABMS) board certification information. For group practices, users can view group practice names, specialties, practice locations, Medicare assignment status, and affiliated professionals. In addition, Medicare professionals and group practices that satisfactorily or successfully participated in a CMS quality program have a green check mark on their profile page to indicate their commitment to quality.

Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare also phased in public reporting of information on physician performance that provides comparable information on quality and patient experience measures for reporting periods beginning January 1, 2012. To the extent that scientifically sound measures are developed and are available, Physician Compare is required to include, to the extent practicable, the following types of measures for public reporting: Measures collected under PQRS and an assessment of efficiency, patient health outcomes, and patient experience, as specified. The first set of quality measures were publicly reported on Physician Compare in February 2014. Currently, Physician Compare publicly reports 14 group practice level measures collected through the Web Interface for groups of 25 or more EPs participating in 2014 under the PQRS and for ACOs participating in the Shared Savings Program or Pioneer ACO program, and six individual level measures collected through claims for individual EPs participating in 2014 under the PQRS. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117–22).

As finalized in the CY 2015 and CY 2016 PFS final rules (79 FR 67547 and 80 FR 70885) Physician Compare will expand public reporting over the next several years. This expansion includes publicly reporting both individual EP and group practice level QCDR measures starting with 2015 individual EP measures to be publicly reported on Physician Compare in late 2016, and expanding to group practice QCDR measures in late 2017 (80 FR 71125), which is consistent with section 101(d)(1)(B) of the MACRA.

Section 1848(q)(9)(A) and (D) of the Act facilitates the continuation of the phased approach to public reporting by requiring the Secretary to make available on the Physician Compare Web site, in an easily understandable format, individual MIPS eligible clinician and groups performance information, including:

- The MIPS eligible clinician's CPS;
- The MIPS eligible clinician's performance under each MIPS performance category (quality, resource use, CPIA and advancing care information);
- Names of eligible clinician's in Advanced APMs and, to the extent feasible, the names of such Advanced APMs and the performance of such models; and
- Periodically post aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinician's and the range of the performance of all MIPS eligible clinician's with respect to each performance category.

Section 1848(q)(9)(B) of the Act also requires that this information indicate, where appropriate, that publicized information may not be representative of the eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated. In order to ensure the information mandated under section 1848(q)(9) of the Act are publicly reported, the information must be in compliance with the existing mandate and regulations previously established under section 10331(a)(2) and 10331(b) of the Affordable Care Act. As required under section 10331(a)(2) of the Affordable Care Act, all measure data included on Physician Compare must be comparable. In addition, section 10331(b) of the Affordable Care Act requires that we include, to the extent practicable, processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary. In addition to the Affordable Care Act informed public reporting standards—statistically valid and reliable data, that are accurate and comparable—existing regulation notes that all the data must also prove through consumer testing to resonate with and be accurately interpreted by consumers in order to be included on Physician Compare profile pages. Together, we refer to these conditions as the Physician Compare public reporting standards (80 FR 71118–20). Section 10331(d) of the Affordable Care Act also requires us to consider input from multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act. We also continue to receive general input from stakeholders on Physician Compare through a variety of means, including rulemaking and different forms of stakeholder outreach (for example, Town Hall meetings, Open Door Forums, webinars, education and outreach, Technical Expert Panels, etc.).

In addition, section 1848(q)(9)(C) of the Act requires the Secretary to provide an opportunity for MIPS eligible clinicians to review the information that will be publicly reported prior to such information being made public. This is generally consistent with section 10331(a)(2) of the Affordable Care Act and current regulations that established a 30-day preview period for all measurement performance data that will allow physicians and other EPs to view their data as it will appear on the Web site in advance of publication on Physician Compare (80 FR 71120). Section 1848(q)(9)(C) of the Act also requires that MIPS eligible clinicians be able to submit corrections for the information to be made public. We propose that this extension of the current Physician Compare 30-day preview period will be implemented starting with data from the 2017 MIPS performance period. We propose a 30-day preview period in advance of the publication of any data on Physician Compare. We will coordinate efforts between Physician Compare and the four components of MIPS in terms of data review and appeal and any relevant data resubmission or correction. All data available for public reporting—measure rates, scores, and/or attestations—will be available for review and correction during the targeted review process (see section II.E.8.c. of this proposed rule). The process will begin at least 30 days in advance of the publication of new data. Data under appeal and review will not be publicly reported until the review is complete. All corrected measure rates, scores, and/or attestations submitted will be available for public reporting. The technical details of the process will be communicated directly to affected MIPS eligible clinicians and groups and detailed outside of rulemaking.

As with the current process, the details will be made public on the Physician Compare Initiative page on cms.gov and communicated through Physician Compare and other CMS listservs.

In addition, section 1848(q)(9)(D) of the Act requires that aggregate information on the MIPS be periodically posted on the Physician Compare Web site; including the range of composite scores for all MIPS eligible clinicians and the range of performance for all MIPS eligible clinicians with respect to each performance category.

Lastly, section 104 of the MACRA requires the Secretary to make publicly available, on an annual basis (beginning with 2015), in an easily understandable format, information with respect to physicians and other eligible clinician's on items and services furnished to Medicare beneficiaries, and to include, at a minimum:

- Information on the number of services furnished under Part B, which may include information on the most frequent services furnished or groupings of services;
- Information on submitted charges and payments for Part B services; and
- A unique identifier for the physician or other eligible clinician that is available to the public, such as an NPI.

The information would further be required to be made searchable by at least specialty or type of physician or other eligible clinician; characteristics of the services furnished (such as, volume or groupings of services); and the location of the physician or other eligible clinician.

Therefore, at § 414.1395(a) we propose public reporting of an eligible clinician's MIPS data; in that for each program year, we would post on a public Web site, in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under the MIPS.

Furthermore, in accordance with section 104(e) of the MACRA, we finalized in the CY 2016 PFS final rule

(80 FR 71130) to add utilization data to the Physician Compare downloadable database. Utilization data is currently available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html.* As finalized (80 FR 71130), this information will be integrated on the Physician Compare Web site via the downloadable database targeted for late 2016. Not all available data will be included. The specific HCPCS codes included will be determined based on analysis of the available data, focusing on the most used codes. Additional details about the specific HCPCS codes that will be included in the downloadable database will be provided to stakeholders in advance of data publication. And, all data available for public reporting—on the consumer-facing Web site pages or in the downloadable database—will be available for preview during the 30-day preview period.

We believe section 10331 of the Affordable Care Act supports our overarching goals of the MACRA by providing consumers with quality information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, section 1848(q)(9) of the Act, and section 104(e) of the MACRA, we plan to continue to publicly report performance information on Physician Compare. As a result, we propose inclusion of the following information on Physician Compare.

a. Composite Score, Performance Categories, and Aggregate Information

As noted, section 1848(q)(9)(A) and (D) of the Act requires that we publicly report on Physician Compare the composite score for each MIPS eligible clinician, performance of each MIPS eligible clinician for each performance category, and periodically post aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category. We propose that these data, to the extent that they meet the previously established public reporting standards, will be added to Physician Compare for each MIPS eligible clinician or group, either on the profile pages or in the downloadable database, as technically feasible. Statistical testing and consumer testing, as well as consultation of the Physician Compare Technical Expert Panel (TEP), will determine how and where these data are reported on Physician Compare. We request comments on these proposals.

In addition, we seek comment on the advisability and technical feasibility of including data voluntarily reported by EPs and groups that are not subject to MIPS payment adjustments, such as those practicing through RHC, FQHCs, etc., on Physician Compare. Any regulatory changes would be made through separate notice-and-comment rulemaking.

b. Quality

The quality performance category is discussed in detail in section II.E.5.b. of this proposed rule. Consistent with the current policy that makes all current PQRS measures available for public reporting, we now propose to make all measures under the MIPS quality performance category (see section II.E.5.b. of this proposed rule) available for public reporting on Physician Compare. This includes all available measures reported via all available submission methods, and applies to both MIPS eligible clinicians and groups.

Also consistent with current policy, although all measures will be available for public reporting not all measures will be made available on the consumer-facing Web site profile pages. As explained in the CY 2016 PFS final rule (80 FR 71120), providing too much information can overwhelm consumers and lead to poor decision making. Therefore, we propose that all measures in the quality performance category that meet the public reporting standards would be included in the downloadable database, as technically feasible. We also propose that a subset of these measures would be publicly reported on the Web site's profile pages, as technically feasible. Statistical testing and consumer testing will determine how and where measures are reported on Physician Compare. In addition, we do not publicly report first year measures, meaning new measures that have been in use for less than 1 year, regardless of submission methods. After a measure's first year in use, we will evaluate the measure to see if and when the measure is suitable for pubic reporting (80 FR 71118).

Currently, there is a minimum sample size requirement of 20 patients for performance data to be included on the Web site. As part of the MIPS and APMs RFI we asked for comment on moving away from this requirement and moving to a reliability threshold for public reporting. In general, commenters supported a minimum reliability threshold. As a result, we are now proposing to institute a minimum reliability threshold for public reporting on Physician Compare.

The reliability of a measure refers to the extent to which the variation in measure is due to variation in quality of care as opposed to random variation due to sampling. Statistically, reliability depends on performance variation for a measure across entities, the random variation in performance for a measure within an entity's panel of attributed beneficiaries, and the number of beneficiaries attributed to the entity. High reliability for a measure suggests that comparisons of relative performance across entities, in this case groups or eligible clinicians, are likely to be stable and consistent, and that the performance of one entity on the quality measure can confidently be distinguished from another. Conducting analysis to determine reliability of the data collected will allow us to calculate the minimum reliability threshold for those data. Once an appropriate minimum reliability threshold is determined, the reporting of reporters' performance rates for a given measure can be restricted to only those meeting the minimum reliability threshold.

We propose to also include the total number of patients reported on per measure in the downloadable database to facilitate transparency and more accurate understanding and use of the data. We request comments on these proposals.

We also are seeking comment on the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the quality performance category. Any regulatory changes would be made in separate notice-and-comment rulemaking.

c. Resource Use

The resource use performance category is detailed in section II.E.5.e. of this proposed rule. We propose to make all measures under the MIPS resource use performance category (see section II.E.5.e. of this proposed rule) available for public reporting on Physician Compare. This includes all available measures reported via all available submission methods, and applies to both MIPS eligible clinicians and groups.

We have found that resource use data do not resonate with consumers and can instead lead to significant misinterpretation and misunderstanding. Therefore, we propose to include a sub-set of resource use measures, that meet the aforementioned public reporting standards, on Physician Compare, either on profile pages or in the downloadable database, if technically feasible. Statistical testing and consumer testing will determine how and where measures are reported on Physician Compare. In addition, we do not publicly report first year measures, meaning new measures that have been in use for less than 1 year, regardless of submission methods. After a measure's first year in use, we will evaluate the measure to see if and when the measure is suitable for pubic reporting (80 FR 71118). We request comments on these proposals.

We also are seeking comment on the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the resource use performance category. Any regulatory changes would be made in separate notice-and-comment rulemaking.

d. CPIA

The CPIA performance category is detailed in section II.E.5.f. of this proposed rule. We propose to make all activities under the MIPS CPIA performance category (see section II.E.5.f. of this proposed rule) available for public reporting on Physician Compare. This includes all available CPIAs reported via all available submission methods, and applies to both MIPS eligible clinicians and groups.

We propose to include a subset of CPIA data that meet the aforementioned public reporting standards, on Physician Compare, either on the profile pages or in the downloadable database, if technically feasible. For those eligible clinicians that successfully meet the CPIA performance category requirements this may be posted on Physician Compare as an indicator. The CPIA performance category is a new field of data for Physician Compare so concept and consumer testing will be needed to ensure these data are understood by consumers. Therefore, statistical testing and consumer testing will determine how and where CPIAs are reported on Physician Compare. In addition, since we do not publicly report first year measures, we are also applying this policy to CPIA, meaning new CPIAs that have been in use for less than 1 year, regardless of submission methods. After a CPIA's first year in use, we will evaluate the activity to see if and when the activity is suitable for pubic reporting (80 FR 71118). We request comments on these proposals.

We also are seeking comment on the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the CPIA performance category. Any regulatory changes would be made in separate notice-and-comment rulemaking.

e. Advancing Care Information

Since the beginning of the EHR Incentive Programs in 2011, participant performance data has been publically available in the form of public use files on the CMS Web site. In the 2015 EHR Incentive Programs final rule, we addressed comments requesting that CMS not only continue this practice but also include a wider range of information on participation and performance. In that rule, we stated our intent to publish the performance and participation data on Stage 3 objectives and measures of meaningful use in alignment with quality programs which utilize publicly available performance data such as Physician Compare (80 FR 62901). At this time there is only a green check mark on Physician Compare profile pages to indicate that an EP successfully participated in the current Medicare EHR Incentive Program for EPs.

As MIPS will now include advancing care information as one of the four MIPS performance categories, we are proposing to include more information on eligible clinician's performance on the objectives and measures of meaningful use on Physician Compare. An important consideration is that to meet the aforementioned public reporting standards, the data added to Physician Compare must resonate with the average Medicare consumer and their caregivers. Consumer testing to date has shown that people with Medicare value the use of certified EHR technology and see EHR use as something that if used well can improve the quality of their care. In addition, we believe the inclusion of indicators for providers who achieve high performance in key care coordination and patient engagement activities provide significant value for consumers.

We are therefore proposing to include an indicator for any eligible clinician or group who successfully meets the advancing care information performance category, as detailed in section II.E.5.g. of this proposed rule, as technically feasible on Physician Compare. Also as technically feasible, we are proposing to include additional indicators, including but not limited to, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange; as further specified in section II.E.5.g. of this proposed rule. To reiterate, any advancing care information objectives or measures must meet the public reporting standards to be posted on Physician Compare, either on the profile pages or in the downloadable database. This includes all available objectives or measures reported via all available submission methods, and applies to both MIPS eligible clinicians and groups. Statistical testing and consumer testing will determine how and where objectives and measures are reported on Physician Compare. In addition, we do not publicly report first year measures, meaning new measures that have been in use for reporting for less than 1 year, regardless of submission methods. After a measure's first year in use, we will evaluate the measure to see if and when the measure is suitable for pubic reporting (80 FR 71118). We request comment on these proposals.

We also are seeking comment on potentially including an indicator to show low performance in the advancing care information performance category, as well as, the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the advancing care information performance category. Additionally, we would need to perform consumer testing and evaluate the feasibility of potentially including an indicator to show low performance in the advancing care information performance category to ensure this is understood by consumers. Any regulatory changes would be made in separate notice-and-comment rulemaking.

f. Utilization Data

As discussed above, we previously finalized to begin to include utilization data in the Physician Compare downloadable database in late 2016 using the most currently available data (80 FR 71130) to meet section 104(e) of the MACRA. As there are thousands of Healthcare Common Procedure Coding System (HCPCS) codes in use, not all available data will be included. The specific HCPCS codes included will be determined based on analysis of the available data, focusing on the most used codes. The goal will be to include counts that can facilitate a greater understanding and more in-depth analysis of the other measure and performance data being made available. We propose to continue to include utilization data in the Physician Compare downloadable database. We request comment on this.

g. APM Data

As discussed above, section 1848(q)(9)(A)(ii) of the Act requires us to publicly report names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of Advanced APMs. We see this as an opportunity to continue and build on reporting we are now doing of ACO data on Physician Compare. At this time, if an EP or group submitted quality data as part of an ACO, there is an indicator on the EP's or group's profile page indicating this. In this way, it is known which EPs and groups took part in an ACO. Also, currently, all ACOs have a dedicated page on the Web site to showcase their data. If technically feasible, we propose to use this model as a guide as we add APM data to Physician Compare. We propose to indicate on eligible clinician and group profile pages when the eligible clinician or group is participating in an APM. We also propose to link eligible clinicians and groups to their APMs data, as relevant and possible, through Physician Compare. Data posting would be considered for both Advanced and non-eligible APMs.

At the outset, APMs will be very new concepts for consumers. Testing shows that at this time, ACOs are not a familiar concept to the average Medicare consumer. It is very easy for consumers to misunderstand an ACO as just a type of group. We expect at least the same lack of familiarity when introducing the broader concept of APM, of which ACOs comprise only one type. In these early years, indicating who participated in APMs and testing language to accurately explain that to consumers provides useful and valuable information as we continue to evolve Physician Compare. As we come to understand how to best explain this concept to consumers, we can continue to assess how to most fully integrate these data on the Web site. We request comment on these proposals.

F. Overview of Incentives for Participation in Advanced Alternative Payment Models

Section 1833(z) of the Act, as added by section 101(e)(2) of the MACRA, requires that an incentive payment be made to Qualifying APM Participants (QPs) for participation in eligible alternative payment models (referred to as Advanced APMs). Key statutory elements of the incentives for participation in Advanced APMs under the Quality Payment Program addressed in this proposed rule include:

- Beginning in 2019, if an eligible clinician participates in a certain type of APM (an Advanced APM), they may become a QP. Eligible clinicians who are QPs are excluded from the MIPS.
- For years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's payments for Part B covered professional services, and beginning in 2026, QPs receive a higher update under the PFS than non-QPs.
- For 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs.
- For 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and APMs with other payers (Other Payer Advanced APMs).
- This section of the rule proposes the definitions, requirements, procedures, and thresholds of participation that will govern this program.

1. Policy Principles

Several core policy principles are derived from both the MACRA law and the Department's broad vision for better care, smarter spending, and healthier people. These principles drive many of our decisions in developing the overall framework for making APM Incentive Payments to QPs and for approaching interactions between MIPS and APMs found in this proposed rule. In addition to increasing the quality and efficiency of care delivered in the Medicare program and across the health system, these principles include the following seven goals:

- To the greatest extent possible, continue to build a portfolio of APMs that collectively allows participation for a broad range of physicians and other practitioners. We believe finding better ways to deliver care across settings and specialties can lead to improved health outcomes and more efficient health care spending. Doing this requires active CMS engagement with stakeholders, as well as input from those stakeholders to refine ideas in ways that meet statutory and delivery system reform goals.
- Design the program such that the APM Incentive Payment is attainable by increasing numbers of practitioners over time, yet remains reserved for those eligible clinicians participating in organizations that are truly engaged in care transformation. We believe the structure of the law is clear in that the APM Incentive Payments are earned through participation in APMs that are designed to be challenging and involve rigorous care improvement activities. In general, we believe eligible clinicians that receive incentives should be those who: Take on financial risk for potential losses under an APM; are accountable for performance based on meaningful quality metrics; and use certified EHR technology.
- Maximize participation in both Advanced APMs and other APMs. Although we want to maintain high standards for eligible clinicians to earn the APM Incentive Payment, we also want to enable and encourage high levels of participation in a broad range of APMs, including those that are not Advanced APMs. We believe participation in any APM offers eligible clinicians and beneficiaries significant benefits.
- Create policies that allow for flexibility in future innovative Advanced APMs. We do not want to constrain the robust development of new Advanced APMs by framing standards only in terms of today's APMs but rather in ways that allow many avenues for meeting the Advanced APM criteria.
- Support multi-payer models and participation in innovative models in Medicaid and commercial markets in order to promote high quality and efficient care across the health care market.
- Recognize that the APM Incentive Payment added by the MACRA primarily incentivizes participation in Advanced APMs that involve covered professional services under Medicare Part B. We believe the new provisions of section 1833(z) of the Act distinguish between participation in Advanced APMs that involve Medicare Part B covered professional services and participation in Other Payer Advanced APMs, which could include those sponsored by Medicare Advantage organizations. The Quality Payment Program has the potential to influence a wide range of payment arrangements, such as those under Medicare Advantage, but there is a clear distinction between Medicare Part B and all other payers in how calculations are performed for QP determinations and the APM Incentive Payment. Through the all-payer route to the APM Incentive Payment, we hope to encourage cooperation across payers and create demand for arrangements that, like Advanced APMs, meaningfully incorporate financial risk, quality measure performance, and use of certified EHR technology as strategies for improving care outcomes.
- Minimize burden on organizations and professionals. Between APM participation and MIPS reporting, we hope to coordinate administrative processes, minimize overall reporting burden, and make transitioning between being a QP and being subject to MIPS as seamless as possible.

- We do not intend to create additional performance assessments or audits beyond those specified under an APM. Rather, we believe the process for determining whether an eligible clinician receives the APM Incentive Payment should focus on the relative degree of participation by eligible clinicians in Advanced APMs, not on their performance within the APM. The Quality Payment Program does not alter how each particular APM measures and rewards success within its design. Rather, it rewards a substantial degree of participation in certain APMs.

2. Overview of Proposed APM Policies

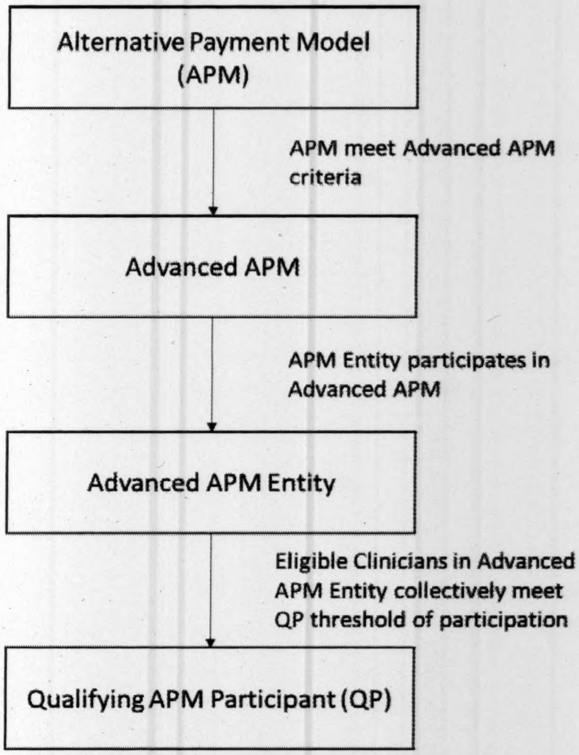
The incentives for Advanced APM participation established by MACRA includes several sets of related requirements that must be met. Three distinct roles play important parts in the program structure: (1) The Advanced Alternative Payment Model (Advanced APM), which is a health care payment and/or delivery model that includes payment arrangements and other design elements as part of a particular approach to care improvement; (2) the Advanced APM Entity, which is the entity participating in the Advanced APM and which meets criteria established under section 1833(z) of the Act; and (3) the eligible clinician, who is the individual physician or practitioner, or group of physicians or practitioners, who is a participant of the Advanced APM Entity and may be determined to be a QP.

In this rule we are proposing a series of steps that result in the determination of certain eligible clinicians as QPs for a particular year (the payment year). QPs would receive the APM Incentive Payment as specified in section 1833(z) of the Act for each of the years they qualify from 2019 through 2024, and the differential update incentive in section 1848(d)(20) of the Act for each of the years they qualify beginning in 2026. Per section 1833(z)(1)(A) of the Act, the APM Incentive Payment that an eligible clinician receives as a QP for a year between 2019 and 2024 is a lump sum payment equal to 5 percent of the QP's estimated aggregate payments for Medicare Part B covered professional services (services paid under or based on the Medicare PFS) for the prior year. Eligible clinicians who are QPs for a year are also excluded from MIPS for that year. In addition, beginning in 2026, QPs receive a higher Medicare PFS update (the "qualifying APM conversion factor") than non-QPs. This QP determination is made for one calendar year at a time.

The proposed steps that would result in a QP determination can be summarized as follows: (1) We determine whether the design of an APM meets three specified criteria for it to be deemed an Advanced APM; (2) an entity (the Advanced APM Entity) with a group of individual eligible clinicians participates in the Advanced APM; (3) we determine whether, during a performance period (the QP Performance Period), the eligible clinicians in the Advanced APM Entity collectively have at least a specified percentage of their aggregate Medicare Part B payments for covered professional services, or patients who received covered professional services, through the Advanced APM; (4) all of the eligible clinicians in the Advanced APM Entity are designated QPs for the payment year associated with that QP Performance Period. Those QPs would receive the 5 percent lump-sum APM Incentive Payments mentioned above for the payment year. This QP determination process would occur each year following the QP Performance Period, with the first payment year being 2019. In section II.F.5.a, we propose that the QP Performance Period will be the calendar year 2 years prior to the payment year.

Under the MACRA, for payment years 2019 and 2020, QP determinations must be based only on payments or patients under Medicare Part B (the Medicare payment threshold option, which we refer to as the "Medicare Option"). Beginning in payment year 2021—which according to our proposal would be based on 2019 calendar year data—there would be an additional option for eligible clinicians to become QPs through a combination of their participation in Advanced APMs and similar payment arrangements with other payers (Other Payer Advanced APMs). This option is the combination all-payer and Medicare payment threshold option, which we refer to as the "All-Payer Combination Option." An eligible clinician need only meet the threshold for one of the options to be a QP for a year. Thus, an Advanced APM Entity may be able to compensate for a relatively low level of Advanced APM participation with participation in Other Payer Advanced APMs such as those with State Medicaid programs and commercial payers. Figure B illustrates the stages of determinations that result in QP determinations.

FIGURE B: Program Overview


Alternative Payment Model (APM)
APM meet Advanced APM criteria
Advanced APM
APM Entity participates in Advanced APM
Advanced APM Entity
Eligible Clinicians in Advanced APM Entity collectively meet QP threshold of participation
Qualifying APM Participant (QP)

3. Terms and Definitions

The proposed Quality Payment Program relies on a set of interrelated defined terms. The bases for some core terms are set forth at sections 1833(z)(3) and 1848(q)(1)(C)(iii) of the Act, and others we will propose to define in this proposed rule.

We use the statutory text as a foundation to develop definitions for other key terms used in this proposed rule. The terms cover three primary topics: (1) The different types of APMs and their participating individuals and entities; (2) the timing, process and thresholds for determining QPs and partial qualifying APM participants (Partial QPs); and (3) the payment of the 5 percent lump sum incentive to QPs.

As discussed in sections II.D and II.F.3 of this proposed rule, we are proposing definitions for the following APM-specific terms at § 414.1302 of new subpart O:

- Affiliated Practitioner.
- APM Entity.
- APM Incentive Payment.
- Attributed beneficiary.
- Attribution-eligible beneficiary.
- Alternative Payment Model (APM).
- Advanced Alternative Payment Model (Advanced APM).
- Advanced APM Entity.
- Episode payment model.
- Incentive Payment Base Period.
- Medicaid APM.
- Medicaid Medical Home Model.
- Medical Home Model.
- Other Payer APM.
- Other Payer Advanced APM.
- Partial Qualifying APM Participant (Partial QP).
- Partial QP Patient Count Threshold.
- Partial QP Payment Amount Threshold.
- Qualifying APM Participant (QP).
- QP Patient Count Threshold.
- QP Payment Amount Threshold.
- QP Performance Period.
- Threshold Score.

To organize the terms, we have proposed the term "Advanced APM" for those APMs defined by section 1833(z)(3)(C) of the Act that meet the criteria under section 1833(z)(3)(D) of the Act. The MACRA uses the term "Eligible APM" in the heading for section 1833(z) of the Act, in section 1848(q)(9)(A)(ii) of the Act, and indirectly defines it at section 1833(z)(3)(D) of the Act as the APMs in which "eligible alternative payment entities" participate. We have decided to use the term "Advanced" in lieu of "Eligible," and rather than referring indirectly, as is done in section 1833(z)(3)(D)(i) of the Act, to the APM in which an eligible alternative payment entity participates, we believe it is essential to the understanding of this proposed rule to be able to identify and propose requirements directly for an Advanced APM.

Similarly, we propose to use the term "Advanced APM Entity" instead of "alternative payment entity" because it highlights the connected but different roles of the Advanced APM (for example, a CMS Innovation Center ACO model meeting specified criteria) and the Advanced APM Entity (for example, a specific ACO participating in that ACO model). We also believe that it is important to the clarity of this proposed rule to define "APM Entity" in addition to "Advanced APM Entity" so that we can easily distinguish between the two under both MIPS and the APM incentives. We propose that an APM Entity would be any participating entity in an APM, whereas we propose that an Advanced APM Entity would be one that participates in an APM that CMS has in fact determined to be an Advanced APM.

We also propose to define the terms "Medical Home Model" and "Medicaid Medical Home Model" as subsets of APMs and Other Payer APMs, respectively. The MACRA provides no definition for the term "medical homes" but makes it an instrumental piece of the law under sections 1848(q)(5)(C)(i), 1833(z)(2)(B)(iii)(II)(cc)(BB), 1833(z)(2)(C)(iii)(II)(cc)(BB), and 1833(z)(3)(D)(ii)(II) of the Act.

We note that medical homes would be the APM Entities in an APM, not the APM itself. The requirements in the MACRA and in this proposed rule actually relate to the disposition of the APM, not the participating medical homes. For instance, as described in section II.F.4.b.(6) of this preamble, section 1115A(c) of the Act relates to the expansion of models (APMs), not the participants (APM Entities) of such models. APM participants are not expanded under section 1115A(c) of the Act. Therefore, we discuss medical homes in terms of the Medical Home Model, which is the concept to which the MACRA and this proposed rule actually refer. Although the definitions are identical but for their payer context, we distinguish Medicaid Medical Home Models because there are specific requirements for them under the determination of Other Payer Advanced APMs as described in section II.F.7.b.(3) of this preamble.

We propose that a Medical Home Model must have the following elements at a minimum:

- Model participants include primary care practices or multispecialty practices that include primary care physician and practitioners and offer primary care services.
- Empanelment of each patient to a primary clinician.

In addition to these elements, we propose that a Medical Home Model must have at least four of the following elements:

- Planned coordination of chronic and preventive care.
- Patient access and continuity of care.
- Risk-stratified care management.
- Coordination of care across the medical neighborhood.
- Patient and caregiver engagement.
- Shared decision-making.
- Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings, population-based payments).

The two required elements are consistent with the fundamental characteristics of medical homes in the various incarnations and accreditation standards across the health care market. Therefore, we believe that an APM cannot be a Medical Home Model unless it has a primary care focus with an explicit relationship between patients and their practitioners. To determine that an APM has a primary care focus, we propose that the Medical Home Model would have to have involve specific design elements related to Eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant. We solicit comments on whether this proposal for determining that an APM has a primary care focus is sufficiently specified.

We believe the optional elements should be present in Medical Home Models, but individually, each is less definitive of a characteristic than the two required elements. We also want to adhere to our principle of enabling future flexibility of APM design. Extensive rigid Medical Home Model criteria would not serve the purpose of promoting the development of new and potentially better ways of managing patient care through primary care.

We seek comment on these elements and which of the elements should be required as opposed to optional. Our proposed definition of Medicaid Medical Home Model is identical to Medical Home Model, except that it specifically describes a payment arrangement operated by a State under title XIX. It is important to separate the terms because Medicaid Medical Home Models have distinct implications in the Other Payer Advanced APM determination and the QP determination under the All-Payer Combination Option.

We believe that these proposed terms and definitions are sufficient to clearly implement the Quality Payment Program. For example, these terms cover all steps of the incentive payment process, from participation in Advanced APMs to QP determinations and payment of incentives. We are aware that this is a complex program and that we are proposing a significant number of terms. We believe that using more distinctive terms is preferable to using fewer terms that could overlap and convey different meanings in different contexts. For instance, Partial QP Patient Count Threshold is a highly specific term, but we believe that it is necessary in context because there are differences between QPs and Partial QPs, and there are differences between the payment amount and patient count thresholds used to determine whether an Eligible clinician becomes a QP or a Partial QP.

We seek comment on these terms, including how we have defined the term, the relationship between terms, any additional terms that we should formally define to clarify the explanation and implementation of this program, and potential conflicts with other terms used by CMS in similar contexts. We also seek comment on the naming of the terms and whether there are ways to name or describe their relationships to one another that make the definitions more distinct and easier to understand. For instance, we would like to know if commenters believe there are more intuitive or efficient terms than those proposed that would still adhere to the statutory language and the intended purposes of the terms. In particular, we would consider options for a framework of definitions that might more intuitively distinguish between APMs and Other Payer APMs and between APMs and Advanced APMs.

We also seek comment on alternative terms or definitions that are both useful in the calculations described in § 414.1430, § 414.1435, § 414.1440, and § 414.1445 of the proposed rule and easily understood by stakeholders.

4. Advanced APMs

The purpose of this section is to define and outline the proposed criteria for Advanced APMs, APMs through which eligible clinicians would have the opportunity to become QPs as specified in section 1833(z)(3)(C) and (D) of the Act. Other Payer Advanced APMs, types of alternative payment arrangements related to the All-Payer Combination Option, are addressed below in section II.F.7 of this preamble.

First, an Advanced APM must, by statute, meet certain requirements, and we propose details for these requirements within this section. First, the broad category of APMs is defined at section 1833(z)(3)(C) of the Act, which states that an APM is any of the following: (i) A model under section 1115A (other than a health care innovation award); (ii) the Shared Savings Program under section 1899; (iii) a demonstration under section 1866C; or (iv) a demonstration required by Federal law.

We believe it necessary to propose additional clarification around the requirements as defined in section 1833(z)(3)(C)(iv) of the Act given the broad scope of programs and demonstrations required by federal legislation that are administered by the Department. We propose that in order to be an APM as a "demonstration required by Federal law," the demonstration must meet the following 3 criteria: (1) The demonstration must be compulsory under the statute, not just a provision of statute that gives the agency authority, but one that requires the agency to undertake a demonstration; (2) there must be some "demonstration" thesis that is being evaluated; and (3) the demonstration must require that there are entities participating in the demonstration under an agreement with CMS or under a statute or regulation. We seek comment on our proposal for these criteria defining a demonstration required under Federal law.

Second, to be considered an Advanced APM, an APM must meet all three of the following criteria, as required under section 1833(z)(3)(D) of the Act. The criteria are:

- The APM must require participants to use certified EHR technology;
- The APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS;
- The APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Act. For a discussion of our proposals for Medical Home Models under this criterion, see section II.F.4.b.(6) of this preamble.

We propose that an APM Entity is the participating entity in an APM that is primarily responsible for the cost and quality of care provided to beneficiaries under the terms of a direct agreement with CMS. The term "eligible alternative payment entity" (which we refer to as an "Advanced APM Entity") is defined under section 1833(z)(3)(D) of the Act. An Advanced APM Entity is an APM Entity that participates in an Advanced APM that, through terms of a Participation Agreement with CMS or through Federal law or regulation, meets the criteria proposed in this rule. In section II.E.2 of this proposed rule, we propose that each unit—APM, APM Entity, and eligible clinician—would be clearly identified in CMS systems by a unique combination of APM identifier/APM Entity identifier/TIN/NPI to be considered for possible determination as an Advanced APM, Advanced APM Entity, or QP, respectively.

In some cases, APMs offer multiple options or tracks with variations in the level of financial risk, or multiple tracks designed for different types of organizations, and we propose to assess the eligibility of each such track or option within the APM independently. For instance, the Medicare Shared Savings Program (Shared Savings Program) has three distinct tracks, the Comprehensive ESRD Care Initiative (CEC) consists of one track for large dialysis organizations and another track for non-large dialysis organizations, and the Next Generation ACO Model has two risk arrangement options that feature different levels of financial risk.

Significant distinctions between the design of different tracks or options may mean that some tracks or options within an APM would meet the proposed Advanced APM criteria while other tracks or options would not. For example, APM Entities may have the option to assume two-sided risk (meaning that they bear a portion of the losses when spending exceeds expectations and share in the savings when spending is below expectations) or one-sided risk (meaning that they share in the savings when spending is below expectations, but do not bear a portion of the losses when spending exceeds expectations) under an APM. If the one-sided risk track does not meet the standard for financial risk as discussed in section II.F.4.b.(3) of this preamble, APM Entities in this track would not be Advanced APM Entities, whereas those in the two-sided risk track could be Advanced APM Entities. In these instances, we propose that we would distinguish that the APM is only an Advanced APM for specific options or tracks.

All entities participating in Advanced APMs are Advanced APM Entities, and distinguishing between the model and the participating entities allows us to directly identify and discuss the requirements unique to each. This approach to identifying Advanced APMs and Advanced APM Entities is also consistent with our proposal for determining QPs, described in section II.F.5 of this preamble, at the Advanced APM Entity level. We believe that because the Advanced APM Entity is the main participant in an Advanced APM, it should therefore be the operative unit by which QP determinations are made.

We propose that an eligible clinician's QP status for a given payment year would be based on a collective evaluation of a group consisting of all eligible clinicians participating in an Advanced APM Entity. All eligible clinicians in an Advanced APM Entity would be identified as participants according to their APM participant identifiers in CMS systems as described in section II.E.2 of this preamble. To attain QP status, we propose that an eligible clinician would have to be listed on December 31 of the QP Performance Period as part of an Advanced APM Entity that, through the collective calculation of all its eligible clinicians, meets the QP Payment Amount Threshold or the QP Patient Count Threshold, both of which are described in section II.F.5 of this preamble. The form and collection of this list is part of the APM's design. For example, an ACO in the Shared Savings Program is comprised of a list of participating Medicare-enrolled TINs (ACO participants) that includes all eligible clinicians, as identified by their NPIs, who bill through those TINs. The group of eligible clinician TIN/NPI combinations determined as of December 31 at the end of each performance year, consistent with the proposals above, would be used to make a QP determination that would apply to all eligible clinicians on the list.

Only eligible clinicians in Advanced APM Entities during the QP Performance Period would have the potential to become QPs and to qualify for the APM Incentive Payment. If the eligible clinicians in the Advanced APM Entity collectively meet the QP Payment Amount Threshold, QP Patient Count Threshold, Partial QP Payment Amount Threshold, or Partial QP Patient Count Threshold criteria as described in section II.F.5 of this preamble, we propose that all of those eligible clinicians in the group defined by the Advanced APM Entity would receive the QP status for the relevant payment year. For example, in the event that a track in the Shared Savings Program is determined to be an Advanced APM and the eligible clinicians in an ACO participating in that track (the Advanced APM Entity) collectively meet the QP threshold criteria, all of the eligible clinicians (as identified by their TIN/NPI combinations) in the ACO would become QPs.

In sections II.F.5 and II.F.8 of the proposed rule, we propose that such QP status would apply to the individual eligible clinician's NPI across all of the TINs to which he or she reassigned the right to receive Medicare payment, not solely to the billing TIN affiliated with the Advanced APM Entity. We believe that this approach is consistent with the statute and prevents situations in which an eligible clinician may be excluded from MIPS for part of his or her practice but still subject to MIPS with respect to another part of his or her practice.

Table 27 illustrates how hypothetical APM designs could intersect with proposed MACRA definitions.

TABLE 27: Examples of Advanced APM Tracks within an APM

Model or Program	Meets Advanced APM criteria?	APM status	Participating entity	Individual	Does Advanced APM Entity eligible clinician group meet QP Threshold?	QP Status of eligible clinicians
Model A Track 1	No	APM	APM Entity	Eligible clinician	NA	Does not qualify
Model A Track 2	Yes	Advanced APM	Advanced APM Entity	Eligible clinician	No	Does not qualify
Model A Track 3	Yes	Advanced APM	Advanced APM Entity	Eligible clinician	Yes	QP

a. Advanced APM Determination

In order to determine Advanced APMs and achieve transparency for the Quality Payment Program, we propose to establish a process by which we identify and notify the public of the APMs (including specific APM tracks or options) that would be considered Advanced APMs for a QP Performance Period. We would post this notification to the CMS Web site prior to the beginning of the first QP Performance Period and update the information on a rolling basis according to the proposals below. We believe that making this information available in an accessible format is important for stakeholders to understand how CMS applies the Advanced APM criteria to existing APMs, and to be informed as early as possible about whether an APM they are considering joining is an Advanced APM. Similar to our stated principles earlier in this preamble, we believe that participation in APMs that are not Advanced APMs would continue to offer significant opportunities to eligible clinicians who are not immediately able or prepared to take on the additional risk and requirements of Advanced APMs.

To determine Advanced APMs, we propose two phases of determination and notice. First, we propose to release an initial set of Advanced APM determinations no later than January 1, 2017, for APMs that will be operating during the first QP Performance Period. Second, for new APMs that are announced after January 1, 2017, CMS would include its Advanced APM determination in conjunction with the first public notice of the model, such as the Request for Applications (RFA) or proposed rule. We propose that determinations of Advanced APMs would be posted on the CMS Web site and updated on an ad hoc basis to the extent feasible, but no less frequently than annually, as new APMs become available and others end or change. Both the initial and ad hoc notifications would contain descriptions of whether each track or option within an APM would result in different Advanced APM statuses. We believe that this proposal incorporates both the interest in immediate dissemination of Advanced APM determinations for the existing APM portfolio following finalization of this rule and the structure for making the Advanced APM status a regular part of the development and release of new APMs in the future.

We seek comment on the proposals for both the initial and ad hoc notices of Advanced APM determinations. In particular, we seek comments on optimal times, locations, formats, and other methods of notice of Advanced APM determinations to promote clarity and consistency around which APMs are considered Advanced APMs for a particular QP Performance Period.

In addition to identifying Advanced APMs, we propose that we would identify Other Payer Advanced APMs. The Other Payer Advanced APM identification process would go into effect starting in the third QP Performance Period (applicable for payment year 2021) and would align with the availability of the All-Payer Combination Option for QP determinations. We propose that Other Payer Advanced APM determinations and associated notice would rely on information submitted by APM Entities and eligible clinicians as described in section II.F.7.d of this preamble and would operate in conjunction with the QP determination process under the All-Payer Combination Option as described in section II.F.7 of this preamble. If the information needed by CMS to make a determination for the Other Payer Advanced APM is not submitted in the manner and by the deadlines set by CMS through subregulatory guidance, we would not assess that Other Payer APM as explained under section II.F.7 of this preamble.

b. Advanced APM Criteria

Under MACRA, for an APM to be an Advanced APM it must meet the criteria set forth in sections 1833(z)(3)(C) and (D) of the Act and discussed below. An Advanced APM must be an APM that:

- Requires its participants to use certified EHR technology (CEHRT), as described in section II.F.4.b.(1) of this preamble;
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS, as described in II.F.4.b(2); and
- EITHER (a) requires its participating Advanced APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, as described in section II.F.4.b(3) of this preamble, or (b) is a Medical Home Model expanded under section 1115A(c) of the Act, as described in section II.F.4.b(4) of this preamble.

These requirements as set forth in the statute and proposed in this section must be met through the design of the APM. Whether an APM is an Advanced APM depends solely upon how the APM is designed, rather than on assessments of participant performance within the APM. Some stakeholders have suggested that actual performance (for example, on clinical quality measures or on whether the Advanced APM Entity generates savings) be considered in the determination of QPs. However, the incentives for Advanced APM participation, as required under section 1833(z) of the Act, does not provide for consideration of actual performance in making such determinations. Performance assessments are already part of APMs, and we believe it is important and consistent with the statutory framework to continue to foster flexibility in structuring the specific rewards and consequences of performance within each APM.

For example, an APM that ties payments to performance on quality measures comparable to those under MIPS may be an Advanced APM regardless of an Advanced APM Entity's actual performance on those quality measures. If an Advanced APM Entity fails to meet quality performance standards under the Advanced APM, it would face consequences within the Advanced APM, such as financial penalties, loss of access to data or certain waivers, or termination of its participation agreement. The termination scenario would have the downstream effect of terminating Advanced APM Entity status and the eligible clinicians' potential eligibility for the APM Incentive Payment because the entity would no longer be participating in the Advanced APM. As another example, an Advanced APM Entity that bears more than nominal financial risk for monetary losses in accordance with the standards set forth in section II.F.4.b.(3) of this preamble would be an Advanced APM Entity regardless of whether it actually earns shared savings or generates shared losses under the Advanced APM. This would work similarly for an Other Payer Advanced APM.

We do not intend to add additional performance assessments on top of existing Advanced APM standards. As stated in the discussion of policy principles at the beginning of section II.F.1 of this preamble, the proposed QP determination process assesses the relative degree of participation of the Advanced APM Entity and eligible clinician in Advanced APMs, not their performance success as assessed under the APM. The Quality Payment Program would not alter how each particular APM measures and rewards success within its design. Rather, the Quality Payment Program rewards a substantial degree of participation in certain APMs.

(1) Use of Certified EHR Technology

The first criterion an APM must meet to be considered an Advanced APM is that it requires participants in such model to use certified EHR technology (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act. Furthermore, to be considered an Other Payer Advanced APM, as described under sections 1833(z)(2)(B)(iii)(II)(bb) and 1833(z)(2)(C)(iii)(II)(bb) of the Act, payments must be made under arrangements in which certified EHR technology is used. Although the statutory requirement is phrased slightly differently for Advanced APMs and Other Payer Advanced APMs, we believe that there is value in keeping the two standards as similar as possible. We received a number of comments on the MIPS and APMs RFI regarding the definition and use of CEHRT by APMs. A number of commenters recommended that CMS use the same CEHRT definition for APMs that is used for the MIPS program to reduce confusion among participants in these programs and to align the program requirements. Some commenters suggested we should not require additional CEHRT requirements for APMs, while others indicated that current health IT is not adequate to support practice transformation efforts to perform as a patient centered medical home. Other commenters indicated the focus should not be on the technology used, but rather the design and purpose of the APM. A few commenters indicated there was a need to develop certified health IT for specialty eligible clinicians. Additionally, psychologists, plastic surgeons, radiologists, and other specialists commented that they did not want to be left out of APMs because they did not have certified health IT meeting the CEHRT definition now or may not use CEHRT for the same functions as other eligible clinicians.

After consideration of these comments, we propose to adopt for Advanced APMs and Other Payer Advanced APMs, the definition of CEHRT that is proposed for MIPS and the APM incentive under § 414.1305. In the 2015 EHR Incentive Programs final rule (80 FR 62872 through 62873), we established the definition of CEHRT for EHR technology that must be used by Eligible Professionals to meet the meaningful use objectives and measures in specific years. In this proposed rule, we are proposing to adopt the specifications from within the current definition of CEHRT in this regulation at § 414.1305 for eligible clinicians participating in MIPS or in APMs. This definition is similar to the definition that applies to eligible hospitals, CAHs, and eligible professionals (EPs) in the EHR Incentive Programs. The definition includes the certification criteria for a wide range of standards for use in capturing patient health information like vital signs, medications and medication allergies, problem list, and lab results among other data elements including the common clinical data set (CCDS). It also includes the certification criteria and standards for functions related to information exchange, patient engagement, quality reporting, and protecting the privacy of electronic protected health information. For further information on the certification criteria see the 2015 Edition Certification Criteria final rule (80 FR 62602 through 62759) and for example Table 8: "Common Clinical Data Set" (80 FR 62696).

This approach aligns the APM health IT certification requirements for Advanced APMs with those used by MIPS eligible clinicians. We understand this proposed CEHRT definition may include some EHR functionality used by MIPS eligible clinicians which may be less relevant for an APM participant, and likewise APM participants may use additional functions that are not required for MIPS participation. However, we observe that APM participants often work in the same office space, group, entity, or organization with eligible clinicians that are not APM participants. At times they might share common resources, such as the same EHR system. Using the same CEHRT definition for both MIPS and Advanced APMs would allow Eligible clinicians to continue to use shared EHR systems and give eligible clinicians flexibility of participation as a MIPS eligible clinician or an eligible clinician in an Advanced APM without needing to change or upgrade EHR systems. Although updates to the certified health IT for APM participants, MIPS participants, or both may be necessary in future years, we believe that aligning the APM and MIPS definition for CEHRT is appropriate at this time.

We seek comment on the proposed definition of CEHRT for Advanced APMs and Other Payer Advanced APMs and whether the definition should be the same for both.

The statute does not specify the number of eligible clinicians who must use CEHRT or how CEHRT must be used in an Advanced APM. We believe CMS has discretion to define the ways in which an Advanced APM uses CEHRT. In accordance with section 1833(z)(3)(D)(i)(I) of the Act, we propose that an Advanced APM must require at least 50 percent of eligible clinicians who are enrolled in Medicare (or each hospital if hospitals are the APM participants) to use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals. Communicating clinical care means that other eligible clinicians and/or the patient can view the clinical care information. Later in this section, we also propose an alternative set of criteria applicable to the Shared Savings Program to demonstrate the use of CEHRT by their eligible clinicians in order to be an Advanced APM. We propose the 50 percent threshold be confined to the first QP Performance Period (proposed later in this rule to be 2017). That is, only in 2017 could APMs use the 50 percent threshold for eligible clinicians in each participating entity to meet the use of CEHRT requirement. We propose that the threshold requirement for use of CEHRT would increase to 75 percent beginning for the second QP Performance Period (proposed to be 2018). The requirement for hospitals participating in Advanced APMs would remain the same over time because it is an all-or-nothing requirement of the hospital as a single entity.

We believe there are a few reasons why having a lower threshold requirement for the use of CEHRT by the eligible clinicians participating in an APM Entity in the first year is appropriate. First, we want to ensure that APMs have sufficient time to alter their terms and conditions to meet this standard. We also acknowledge that eligible clinicians will be expected to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2018, and some eligible clinicians who have not yet adopted CEHRT may wish to delay acquiring CEHRT products until a 2015 Edition certified product is available.

Although these are important considerations for the first year of the program, we believe that APMs should expect their APM Entities to meet a higher standard for the use of certified EHR technology in future years. We note that several APMs that are likely to meet the other criteria to be an Advanced APM have already demonstrated higher rates of achievement of meaningful use under the EHR Incentive Program that exceed the requirements under the APM. For instance, an analysis of 2014 performance year quality reporting data under the SSP showed that an average of 86 percent of primary care physicians met meaningful use requirements in 2014 (See *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-25.html*). Other APMs require all eligible clinicians to use CEHRT as a requirement for participation in the APM. We believe that, based on the focus of an Advanced APM, this criterion should challenge APMs and their participants to adopt CEHRT at high rates and use its capabilities to deliver high value care. The adoption of CEHRT is critical to supporting increased care coordination, electronic clinical quality measure reporting, electronic clinical decision support, and many other capabilities supportive of success in APMs, and we believe these capabilities should be widely available to eligible clinicians participating in APMs. Therefore, we believe that raising the threshold for use of CEHRT required to be an Advanced APM would be appropriate for future years beginning in QP Performance Period 2018.

Stakeholders should keep in mind that this CEHRT requirement would be based on the requirements that an APM places on its participating APM Entities. In determining whether an APM meets this criterion, CMS does not propose to assess the level of use of each APM Entity or individual eligible clinician participating in the APM but rather whether the APM requirements meet the standard set forth in this proposed rule.

We invite comment on whether the proposed thresholds for use of CEHRT for APM Entities that are not hospitals (50 percent for the first QP Performance Period (proposed 2017) and 75 percent for the second QP Performance Period (proposed 2018) and later are appropriate, or if we should consider additional options such as a higher or lower percentage in 2018, or an additional incremental increase for 2019. We also invite comment on whether we should consider higher thresholds for APMs that target eligible clinician populations with higher-than-average adoption of certified health IT, such as eligible clinicians in patient-centered medical homes. Finally, we invite comment on whether we should explore ways to set lower thresholds for those APMs targeting eligible clinician populations that may have lower average adoption of certified health IT, such as specialty-focused APMs.

We also propose an alternative criterion for determining whether an APM meets the CEHRT requirement, exclusively applicable for the Shared Savings Program. We believe this method is appropriate for the Shared Savings Program because although the Shared Savings Program requires ACOs to encourage and promote the use of enabling technologies (such as EHRs) to coordinate care for assigned beneficiaries, the Shared Savings Program does not require a specific level of CEHRT use for participation in the program. Instead, the Shared Savings Program includes an assessment of EHR use as part of the quality performance standard which directly impacts the amount of shared savings/losses generated by the Shared Savings Program ACO. We believe it is important to incentivize ever-increasing level of CEHRT use. However, in contrast to CMS APMs under section 1115A of the Act, CMS would have to undertake significant rulemaking to adopt an eligibility standard for the Shared Savings Program that is consistent with the proposed criterion for other CMS APMs. Following such rulemaking, we would have to collect additional information from each existing and applying ACO outside the routine application process in the weeks prior to the start of the 2017 performance year which we believe could introduce uncertainty and burden for CMS, ACOs, and participating EPs. Moreover, we believe that the proposed alternative criterion builds on established Shared Savings Program rules and incentives that directly tie the level of CEHRT use to the ACO's financial reward which in turn has the effect of directly incentivizing ever-increasing levels of CEHRT use among EPs. We believe that the proposed alternative criterion for the Shared Savings Program is consistent with the goals of the APM incentive and reduces burden and uncertainty for the Shared Savings Program participants. Therefore, because most other APMs can accommodate a new CEHRT use requirement for eligible clinicians without modifying our regulations, we are restricting this method to the Shared Savings Program. We propose that this alternative would allow the Shared Savings Program to meet the criterion if it holds APM Entities accountable for their eligible clinicians' use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use (such as the percentage of eligible clinicians that use CEHRT or the engagement in care coordination or other activities using CEHRT). One of the quality measures used in the Shared Savings Program's quality performance standard assesses the degree to which certain eligible clinicians in the ACO successfully meet the requirements of the EHR Incentive program, which requires the use of CEHRT by certain eligible clinicians in the ACO. Successful reporting of the measure for a performance year gives the ACO points toward its overall quality score, which in turn affects the amount of shared savings or shared losses an ACO could earn or be liable for, respectively. Because of this, ACOs in the Shared Savings Program actively promote and seek to improve upon the EHR measures annually, leading to greater use of CEHRT among eligible clinicians participating in Shared Savings Program ACOs. We believe our proposed criteria for APMs, generally, and our alternative for the Share Savings Program, would meet the statutory requirement of section 1833(z)(3)(D)(i)(I) of the Act, as both hinge upon the Advanced APM requiring its participants use CEHRT with consequences for failure to meet the APM's standards. We solicit comment on our proposed methods for meeting the criterion for an Advanced APM to require its participants to use CEHRT as specified in section 1833(z)(3)(D)(i)(I) of the Act.

In addition to these proposals, we are interested in what other health IT functionalities APM participants might need to effectively provide care to their patients and how the use of interoperable health IT can strengthen and encourage higher quality patient care and more effective care coordination across all APMs. Recent research and input from experts, practitioners, and the public (See *https://www.healthit.gov/facas/sites/faca/files/HITPC_AHMWG_Meeting_Slides_Final_Version_9_2015-11-10.pdf*) has identified priority health IT capabilities that will be important for participants in APMs but are not yet widely available in current health IT systems, such as the ability to manage and track status of referrals and create and maintain electronic shared care plans for team-based care management.

We look forward to receiving comments as to whether new health IT standards and certification criteria may be needed to ensure that participants in APMs have access to interoperable health IT products and services necessary for effective care coordination, population health management, and patient engagement. We will work with the Office of the National Coordinator (ONC) to explore opportunities for certified health IT capabilities reflected in the CEHRT definition to evolve in ways that meet the needs of participants in APMs while supporting eligible clinicians in MIPS to fulfill the EHR performance category under MIPS.

We believe that all patients, families, and healthcare professionals should have consistent and timely access to health information in a standardized format that can be securely exchanged between these parties (See HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange"). The secure, appropriate exchange of health information can help health care professionals improve quality of care through more robust care coordination, and improve the efficiency of care through access to patient information across settings. Interoperability is a key priority for the healthcare industry. HHS recently received pledges from companies that provide 90 percent of the electronic health records used by hospitals nationwide, as well as the top five largest health care systems in the country, to: help consumers easily and securely access their electronic health information; help clinicians share individuals' health information for care with other clinicians and their patients whenever permitted by law and not block electronic health information; and implement federally recognized, national interoperability standards, policies, guidance, and practices for electronic health information.

A growing number of organizations across the country are now focused on facilitating health information exchanges (HIEs) among healthcare professionals at the national, state, and community levels. According to one figure, there were 267 organizations providing HIE services operating in the U.S. in 2014 (see *https://ehi-rails-app.s3.amazonaws.com/uploads/article/file/476/2014_eHI_Data_Exchange_Survey_Results_Webinar_Slides.pdf*), including community-based organizations, statewide efforts, and other healthcare delivery entities supporting exchange. While representing a wide variety of stakeholders, services and structures, these organizations play an important role in facilitating care coordination and data sharing for many health care professionals across the country. We encourage the growth of these services and encourage healthcare professionals to explore partnering with organizations offering HIE services.

We seek comment on how requirements for the use of CEHRT within APMs could evolve to support expanded participation in organizations supporting HIEs. For instance, should CMS consider expanding in future rulemaking the CEHRT criterion for Advanced APMs to include recognition of participation with an organization providing HIE services? Would this option be likely to spur further interest among entities in partnering with organizations that provide HIE services? Should these organizations be required to adhere to specific standards that promote interoperability across health information systems? How could a potential future governance mechanism for HIE (that is, establishing a common set of standards, services, policies, and practices) be incorporated into requirements for APMs? We seek comment on these and any other issues related to advancing participation in HIEs though the use of CEHRT in APMs.

(2) Comparable Quality Measures

The second criterion for a APM to be an Advanced APM is that it provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) of the Act, which is the MIPS quality performance category. We interpret this criterion to require the APM to incorporate quality measure results as a factor when determining payment to participants under the terms of the APM.

Our proposed policy for this criterion is informed by our proposed policy for the MIPS quality performance category. For more information on quality measures under the MIPS quality performance category, please see section II.E.3.b of this preamble of this preamble, in which CMS proposes eligible clinicians will select quality measures from the MIPS measures list in section II.E.3 of this preamble for the first performance year of MIPS. We will publish a list of quality measures annually, through notice and comment rulemaking, from which MIPS eligible clinicians may choose measures for assessment under the MIPS quality performance category. The measures included in the annual list of MIPS measures must adhere to specific criteria that include the following: (1) Measures must have an evidence-based focus if the measures are not endorsed by a consensus-based entity as described in section 1848(q)(2)(D)(v) of the Act; and (2) new measures and the method for developing and selecting such measures, including clinical and other data supporting such measures, must be submitted to a specialty-appropriate, peer-reviewed journal prior to inclusion of the measure in MIPS as described in section 1848(q)(2)(D)(iv) of the Act.

The statute also establishes priorities for both the quality domains of measures to be developed and the types of measures to be prioritized in the measure development plan, which are located, respectively at sections 1848(s)(1)(B) and (D) of the Act. The priority measure types include outcome, patient experience, care coordination, and measures of appropriate use of services such as measures of overuse.

We are considering a number of ways to implement the Advanced APM requirement to base payment on measures comparable to those in MIPS, as well as how to define which measures would reflect the statutory requirement to be "comparable" to MIPS quality measures. Some of the options we explored for defining measures comparable to those in MIPS included: (1) Limiting comparable measures to those from the annual MIPS list of measures; and (2) including quality measures from the annual MIPS list of measures and/or measures that have an evidence-based focus and are found to be reliable and valid through measure testing. We also explored whether we should require a minimum number of measures for all Advanced APMs, and whether the number of measures would need to be the same as those required under the MIPS quality performance category.

In exploring these options we decided that while they all have merit, we are concerned they may be overly restrictive for the variety of APMs, many of which are designed to have the flexibility to test new ways of paying for and delivering care. We want to ensure that APMs have the latitude to base payment on quality measures that meet the goals of the model and assess the quality of care provided to the population of patients that the APM participants are serving. It is important to note that many APMs include some common measures that are proposed for inclusion in MIPS. For example, many of the quality measures used in the Shared Savings Program and the Next Generation ACO Model that are submitted to CMS through the CMS web interface, are also proposed for inclusion in MIPS.

However, APMs that focus on patients with specific clinical conditions, such as end-stage renal disease or patients undergoing specific surgical procedures, would have valid reasons for including different quality measures than those that target more general populations. Similarly, some models may focus on specialist eligible clinicians for whom there may be only a small number of valid and relevant quality measures. Lastly, we cannot predict the specific care goals and payment designs of future physician-focused payment models and other APMs. Consequently, we do not want to impose measure requirements that may prevent CMS from including quality measures that may be better suited to the specific aims of new innovative APMs.

We received a number of comments on the MIPS and APMs RFI on the use of MIPS-comparable quality measures by an Advanced APM. A commenter suggested CMS include high-value performance measures to assess and improve the quality of care that are clinically important, evidence-based, transparent, feasible, valid and reliable, actionable, and rigorously audited to ensure accuracy. Other commenters indicated APMs should not be required to have the same reporting requirements as is required under the quality reporting performance category for MIPS because each APM is designed differently and may be developed with a specific specialty or condition in mind, so broad reporting requirements would not be relevant. Commenters also indicated the need for measures that could be used across APMs and MIPs to reduce the eligible clinician's reporting burden when switching from one program to the other.

After consideration of the comments and the options above, we recognize the need to propose a measure framework for comparable measures that reflects a few key principles. For the Advanced APM measures to be comparable to MIPS measures, the measures should have an evidence-based focus and as appropriate, target the same priorities, (for example, clinical outcomes, use and overuse). However, as each APM Entity is different, there needs to be the flexibility to determine which measures are most appropriate for use in their respective APM for the purpose of linking those measures to payment under the model. We agree that measures that could be used in both MIPS and APMs is beneficial to eligible clinicians who may switch from one program to the other, but we also do not want to restrict APMs from including new innovative measures that may not be included in MIPS initially, or until later years of the program.

We also note that under the MACRA and in this proposal, not all quality measures under which an APM is assessed are required to be "comparable" and not all payments under the APM must be based on comparable measures. However, at least some payments must be tied to measures comparable to MIPS, regardless of whether those comparable measures are the only ones the APM uses. Under this proposal, APMs retain sufficient freedom to innovate in paying for services and measuring quality. For instance, an APM may have incentive payments related to quality, total cost of care, participation in learning activities, and adoption of health IT. The existence of all of the payments associated with non-quality aspects does not preclude the APM from meeting this Advanced APM criterion. In other words, this criterion only sets standards for payments tied to quality measurement, not other methods of payment. Conversely, an APM may, as current models at the CMS Innovation Center currently do, test new quality measures that do not fall into the MIPS-comparable standard. So long as the APM meets the requirements set forth in this criterion, there is no additional prescription for how the APM tests additional measures that may or may not meet the standards under this criterion. Therefore, we propose that the quality measures on which the Advanced APM bases payment must include at least one of the following types of measures provided that they have an evidence-based focus and are reliable and valid:

(1) Any of the quality measures included on the proposed annual list of MIPS quality measures;

(2) Quality measures that are endorsed by a consensus-based entity;

(3) Quality measures developed under section 1848(s) of the Act;

(4) Quality measures submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(5) Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

We believe that quality measures that are endorsed by the National Quality Forum would meet these criteria. We also propose to establish an Innovation Center quality measure review process for those measures that are not NQF-endorsed or included on the final MIPS measure list to assess if the quality measures have an evidence-based focus, and are reliable and valid. For example, the Comprehensive ESRD Care Model includes NQF #0226 Influenza Immunization for the ESRD Population which is not a measure included for reporting in MIPS but meets the proposed criteria for MIPS-comparable quality measures. We believe under the proposed categories above MIPS-comparable quality measures may include measures that are fully developed after being tested in an APM and found to be reliable and valid. Similarly, we believe that MIPS-comparable quality measures may include QCDR measures provided that the QCDR measures used by the Advanced APM for payment have an evidence-based focus and are reliable and valid.

The statute identifies outcome measures as a priority measure type and we want to encourage the use of outcome measures for quality performance assessment in APMs. Therefore, we propose that in addition to the general comparable quality measure requirements proposed in this section, an Advanced APM must include at least one outcome measure if an appropriate measure (that is, the measure addresses the specific patient population and is specified for the APM participant setting) is available on the MIPS list of measures for that specific QP Performance Period, determined at the time when the APM is first established. If there is no such measure available on the MIPS list at the time the APM is established, then CMS would not require an outcome measure be included after APM implementation.

We believe that this framework would provide the flexibility needed to ensure APM quality performance metrics meet the APM's goals. We invite comments on whether measures to be considered comparable to MIPS should all be reliable and valid and have an evidenced-based focus.

(3) Financial Risk for Monetary Losses

(a) Overview

The third criterion that a APM must meet to be an Advanced APM is that it must either be a Medical Home Model expanded under section 1115A(c) of the Act as described below, or the APM Entities under the APM must bear financial risk for monetary losses under such APM that are in excess of a nominal amount. We will refer to the latter criterion as the "financial risk criterion." The proposed correlating financial risk criterion for Other Payer Advanced APMs is described in section II.F.7 of this preamble with the requirements for consideration under the All-Payer Combination Option that is applicable in payment years 2021 and later.

The proposed financial risk criterion for Advanced APMs would apply to the design of the APM financial risk arrangement between CMS and the participating APM Entity. If the structure of the arrangement meets the proposed financial risk requirements, then this criterion would be met. This proposal would not impose any additional performance criteria related to bearing financial risk. For example, eligible clinicians under the Advanced APM Entity would not need to bear financial risk under the APM so long as the APM Entity bears that risk. Furthermore, an APM Entity would not need to actually achieve savings or other metrics for success under the APM in order for the APM to meet this criterion.

This discussion is broken into two main topics: (1) What it means for an APM Entity to bear financial risk for monetary losses under a APM; and (2) what levels of risk CMS would consider to be in excess of a nominal amount. In developing our proposed policies we prioritized keeping these standards consistent across different types of APMs, including Other Payer Advanced APMs as described in section II.F.7.b.(6) of this preamble. We believe that keeping these standards consistent to the extent possible would make it easier for stakeholders, APM Entities, and eligible clinicians to understand the type of financial risk required in order for an APM to be an Advanced APM. However, we do propose to specify small variations in the requirements in order to accord with the differing characteristics of certain types of APMs.

In particular, we propose specific standards that would apply for Medical Home Models. We believe that, given the unique financial risk and nominal amount standards we are proposing for Medical Home Models in this section below, it would be appropriate to impose size and composition limits for the Medical Home Models to which the unique standards would apply in order to ensure that the focus is on organizations with a limited capacity for bearing the same magnitude of financial risk as larger APM Entities do. We propose that beginning in the second QP Performance Period (proposed to be 2018), the Medical Home Model financial risk standard and nominal amount standard, described in section II.F.4.b.(4) of this preamble, would only apply to APM Entities that participate in Medical Home Models and that have 50 or fewer eligible clinicians in the organization through which the APM Entity is owned and operated. Thus, in a Medical Home Model that is an Advanced APM, the proposed Medical Home Model financial risk and nominal amount standards would only apply to those APM Entities owned and operated by organizations with 50 or fewer eligible clinicians. We believe it is appropriate to use eligible clinicians, rather than physicians, when setting this threshold as the number of eligible clinicians both reflects organizational resources and capacity and also may fluctuate widely around a specific number of physicians. We also believe that this size threshold of 50 eligible clinicians is appropriate because organizations of that size have demonstrated the capacity and interest in taking on higher levels of two-sided risk either by themselves or by joining with other organizations. In the event that a Medical Home Model happens to meet the generally applicable financial risk and nominal amount standards, this organizational size limitation would be moot.

Measuring organizational size based on the size of the "parent organization" differs from measuring it based on the size of the APM Entity. Collecting accurate information on the number of eligible clinicians affiliated with a parent organization will require additional, but we believe achievable, reporting by APM Entities. We believe that size of the organization is generally a better indication of risk-bearing capacity than APM Entity size. For instance, an APM Entity may be very small if it represents one practice site, but that practice site may be one of many affiliated with a health system or independent physician association of substantial size. We believe that the proposed limits on the types and sizes of entities that can be Advanced APM Entities under Medical Home Models will encourage larger organizations to move into Advanced APMs with greater levels of risk than the smaller levels that could enable Medical Home Models to become Advanced APMs. This is consistent with our goals that the incentives for Advanced APM participation should reward commitment to challenging models. However, we do not intend to imply that participation in Medical Home Models is necessarily inappropriate for larger organizations. We recognize that Medical Home Models differ from other APMs, such as ACO initiatives, because Medical Home Models focus on improving primary care through much more targeted and intensive interventions than those commonly found in other APMs. We hope to encourage participation in Medical Home Models for all organizations that can derive value from their designs, not just those that are too small to join ACO initiatives and other higher risk APMs.

We propose implementing this size limitation for Advanced APMs that are Medical Home Models beginning in the second year of the Quality Payment Program (proposed QP Performance Period 2018) because we understand that applications for many APMs will be due to CMS before this rule will be finalized, precluding APM Entities from having time to substantially adjust their APM participation strategies for the 2017 QP Performance Period. We propose that CMS would make a determination of whether an APM Entity meets the size limitation prospectively before a QP Performance Period, and that the determinations would not subsequently change based on changes in organizational size during or after the QP Performance Period (although changes in organizational size would, as applicable, affect determinations for subsequent QP Performance Periods). We want all organizations to have the greatest amount of knowledge possible about their APM participation options prior to making the important decision of which APM or APMs to pursue.

We seek comment on this proposal, particularly with regard to the use of the count of eligible clinicians in the parent organization of the APM Entity as the metric of organizational size for Medical Home Models, and whether setting the limit at 50 for the number of eligible clinicians in the organization would constitute a reasonable threshold to distinguish between organizations that we could expect to have the financial capability to join APMs, such as ACO initiatives, that have two-sided risk. We also seek comment on an alternative option to establish the size limitation based on the number of eligible clinicians in the Medical Home Model, rather than on number of eligible clinicians in the APM Entity's organization. Under this alternative option, we would modify the Medical Home Model definition so that an APM could only be considered a Medical Home Model if no more than 10 percent of eligible clinicians (or, alternatively, 10 percent of APM Entities) in the APM are part of parent organizations with more than 50 eligible clinicians. If this element of the Medical Home Model definition were met (along with all other Medical Home Model elements), all APM Entities participating in the APM would be considered medical homes regardless of their size. Conversely, if more than 10 percent of eligible clinicians (or alternatively, 10 percent APM Entities) participating in the APM are part of parent organizations with more than 50 eligible clinicians, the entire APM would not be a Medical Home Model, and, in the event that the APM does not meet the generally applicable Advanced APM financial risk criterion, none of the participating APM Entities would be Advanced APM Entities.

(b) Bearing Financial Risk for Monetary Losses

In this section, we propose a generally applicable financial risk standard for Advanced APMs and a unique standard that would apply only for Advanced APMs that are identified as Medical Home Models.

(i) Generally Applicable Advanced APM Standard

First, we propose that the generally applicable financial risk standard for Advanced APMs would be that an APM must include provisions that, if actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified performance period, CMS can:

- Withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians; or
- Require the APM Entity to owe payment(s) to CMS.

The proposed financial risk standard for Advanced APMs reflects our interpretation of the statutory requirement that Advanced APM Entities must bear financial risk for monetary losses to encompass "losses" that could be incurred through either direct repayments to CMS or reductions in payments for services. The former would cover two-sided risk arrangements such as shared savings initiatives in which an Advanced APM Entity may receive shared savings or be liable for shared losses. The latter would cover a range of alternative methods for linking performance to payment, such as payment withholds subject to successful performance, or discounts in payment rates retrospectively applied at reconciliation similar to those in many episode-based bundled payment models. We note that the proposed generally applicable financial risk standard would not include reductions in bonus payments—such as shared savings payment incentives that vary based on quality performance—whereas, as described below, the Medical Home Model financial risk standard could be satisfied by such reductions in bonus payments if appropriate conditions are met. As such, except when the Medical Home Model standard applies, one-sided risk arrangements would not meet this financial risk criterion.

We believe that statute supports a financial risk criterion that should be met only by those APMs that are most focused on challenging organizations, physicians, and practitioners to assume financial risk and provide high-value care. Our proposal reflects our belief that more and more APMs will meet this high bar over time. In response to the MIPS and APMs RFI, many stakeholders commented that business risk should be sufficient to meet this financial risk criterion to be an Advanced APM. We also considered whether the substantial time and money commitments required by participation in certain APMs would be sufficient to meet this financial risk criterion. However, we believe that financial risk for monetary losses under an APM must be tied to performance under the model as opposed to indirect losses related to financial investments APM Entities may make. The amount of financial investment made by APM Entities may vary widely and may also be difficult to quantify, resulting in uncertainty regarding whether an APM Entity had exceeded the nominal amount required by statute. In addition to the difficulty in creating an objective and enforceable standard for determining whether an entity's business risk associated with the Advanced APM exceeds a nominal amount, we strongly believe that the statutory scheme under section 1833(z) of the Act recognizes that not all APMs will meet this criterion. We do not intend for our proposal to diminish the substantial time and money commitments in which APM Entities invest in order to become successful participants. We welcome comments on how we could potentially create an objective and meaningful financial risk criterion that would define financial risk for monetary losses based on performance under the APM differently.

(ii) Medical Home Model Standard

Second, we propose to adopt a slightly different financial risk standard for Medical Home Models. For a Medical Home Model to be an Advanced APM, it must include provisions that potentially:

- Withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- Require the APM Entity to owe payment(s) to CMS; or
- Lose the right to all or part of an otherwise guaranteed payment or payments, if either:
- Actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified performance period; or
- APM Entity performance on specified performance measures does not meet or exceed expected performance on such measures for a specified performance period.

With regard to the proposed financial risk standard for Medical Home Models, we believe that the Medical Home Model is a unique type of APM that is treated differently under both the MIPS and APM programs. For example, under the MIPS clinical practice improvement activity performance category, as described in section II.E.3.f of this preamble of this proposed rule, eligible clinicians participating in medical homes receive an automatic 100 percent score, whereas eligible clinicians participating in other APM Entities receive a minimum of a 50 percent score. Additionally, both Medical Home Models and Medicaid Medical Homes Models are distinct from other APMs in that, if they are models tested under section 1115A of the Act, there is the possibility of having an alternate pathway through expansion under section 1115A(c) of the Act to meet the financial risk criterion, and Medicaid Medical Home Models play a role in whether Medicaid payments or patients are excluded in the All-Payer Combination Option for QP determinations (see sections 1833(z)(2)(B)(ii)(I)(bb) and (iii)(II)(cc)(BB), 1833(z)(2)(C)(ii)(I)(bb) and (iii)(II)(cc)(BB), 1833(z)(3)(C)(ii)(II), and 1848(q)(5)(C)(i) of the Act). Medical Home Models and their APM Entities (medical homes) are different from other APMs in that: (1) Medical homes tend to be smaller in size and have lower Medicare revenues relative to total Medicare spending than other APM Entities, which affects their ability to bear substantial risk, especially in relation to total cost of care; and (2) to date, neither publicly nor commercially-sponsored medical homes have been required to bear the risk of financial loss, which means the assumption of any financial risk presents a new challenge for medical homes. For example, a common group practice in the Comprehensive Primary Care (CPC) initiative may consist of less than twenty individuals, including physicians, non-physician practitioners, and administrative staff. Making large lump sum loss payments or going without regular payment for a substantial period of time could put such practices out of business, whereas large ACOs may comprise an entire integrated delivery system with sufficient financial reserves to weather direct short-term losses.

We therefore believe that the unique characteristics of Medical Home Models warrant the application of a financial risk standard that reflects these differences in order to provide incentives for participation in the most advanced financial risk arrangements available to medical homes practitioners.

The proposed financial risk standard for Medical Home Models is similar to the generally applicable Advanced APM standard in its first three conditions. The difference is in the inclusion of the fourth condition for the proposed financial risk standard for Medical Home Models, which would allow a performance-based forfeiture of part of all of a payment under an APM to be considered a monetary loss. For example, a Medical Home Model would meet this standard if it conditions the payment of some or all of a regular care management fee to APM Entities upon meeting specified performance standards. Because the APM does not require any direct payment or repayment to CMS, a medical home penalized in such a manner would not necessarily be in a weaker financial position than it had been prior to the decreased payment; however, it would be in a comparatively worse position in the future than it otherwise would have been had it met performance standards. We believe that this financial risk standard respects the unique challenges of medical homes in bearing risk for losses while maintaining a more rigorous standard than business risk.

We seek comment on the proposed standards set forth for both Advanced APM Medical Home Models and for all other APMs. We would consider any comments on alternative standards suggested by the public that could achieve our stated goals and the statutory requirements. We also seek comment on types of financial risk arrangements that may not be clearly captured in this proposal.

(4) Nominal Amount of Risk

If the APM risk arrangement meets the proposed financial risk standard, we would then consider whether the amount of the risk is in excess of a nominal amount in order for this Advanced APM criterion to be met. We believe the statutory requirement that an APM Entity bear risk under an APM in excess of a nominal amount (which we will term the "nominal amount standard") relates to a particular quantitative risk value at which CMS would consider the risk arrangement to involve potential losses of more than a nominal amount. Similar to the financial risk portion of this assessment, we propose to adopt a generally applicable nominal amount standard for Advanced APMs and a unique nominal amount standard for Medical Home Models. Under the generally applicable nominal amount standard, the total risk percentages are of the APM Entity benchmark or, in the case of episode payment models, the target price, which is the amount of Medicare expenditures (which can vary as to the involvement of Parts A and B depending on the APM) above which an APM Entity owes losses and below which an APM Entity earns savings. In the case of Medical Home Models, the risk percentages for Medical Home Models are based on Medicare Parts A and B revenue. As an alternative, we considered assessing total risk under the generally applicable nominal amount standard (for APM other than episode payment models) in relation to the APM Entity's Parts A and B revenue instead of in relation to the APM benchmark. We note that the ratio between entity revenue and the expenditures reflected in an APM's benchmark may vary across different types of entities, such as when the APM benchmark is based on total cost of care. However, we are not proposing the alternative of basing the generally applicable standard on Parts A and B revenue because that policy would prevent a general determination that an APM meets such standards. Instead, it would require case-by-case determinations at the APM Entity level that could change from year to year. We are also concerned that assessing total risk based on an APM Entity's revenue instead of the APM benchmark would set meaningfully different standards for different types of entities regarding the extent to which they must be held financially responsible if expenditures exceed the benchmark. In general, we believe we should apply a common standard to all types of entities. That being said, we understand that setting the total risk standard too high could create challenges for smaller organizations for which a total cost of care benchmark represents more risk in relation to revenue than it does for larger organizations.

(a) Advanced APM Nominal Amount Standard

In general, we believe that the meaning of "nominal" is, as plain language implies, minimal in magnitude. However, in the context of financial risk arrangements, we do not believe it to be a mere formality. For instance, we do not believe the law was intended to consider one dollar of risk to be more than nominal. That would create an arbitrary distinction between an APM that has only upside reward potential and one that has the same upside reward potential with a fractional and relatively meaningless downside risk. Therefore, in arriving at the proposed values, we sought amounts that would be meaningful for the entity but not excessive. As reference points to anchor the proposed values, we used the percentage amounts of MIPS adjustments in the MACRA and surveyed current APM risk arrangements, including those in Tracks 2 and 3 of the Shared Savings Program, the Pioneer ACO Model, and the Bundled Payments for Care Improvement (BPCI) Initiative. We consider the potential losses and marginal risk rates of those initiatives to be optimal in that they have been vetted through the APM development process and determined to be the appropriate amount of risk for each initiative such that, in the context of the APM, it is anticipated that the amount of risk would motivate the desired changes in care patterns in order to reduce costs and improve quality. As stated above, we believe that the term "nominal" is clearly an amount that is lower than optimal but substantial enough to drive performance. In other words, we are confident that risk levels in current APMs with downside risk are sufficient for a wide variety of providers and suppliers, but in certain circumstances, we would want to encourage participation in APMs with slightly lower levels of risk, though not levels of risk that are so low that an APM becomes no more effective at motivating desired changes than APMs with no downside risk.

Except for risk arrangements described under section II.F.4.b.(4) of this preamble, we propose to measure three dimensions of risk described in this section to determine whether an APM meets the nominal amount standard: (a) Marginal risk, which is a common component of risk arrangements—particularly those that involve shared savings—that refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (b) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (c) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM. Except for risk arrangements described under section II.F.4.b.(3) of this preamble, we propose that for a APM to meet the nominal amount standard the specific level of marginal risk must be at least 30 percent of losses in excess of expected expenditures, and a minimum loss rate, to the extent applicable, must be no greater than 4 percent of expected expenditures, and total potential risk must be at least 4 percent of expected expenditures. As described in greater detail in section II.F.7 of this preamble, the proposed Other Payer Advanced APM nominal risk standard parallels the standard described here for Advanced APMs. In general, we define expected expenditures to be the level of expenditures reflected in the APM benchmark. However, for episode payment models, we defined expected expenditures to be the level of expenditures reflected in the target price.

To determine whether an APM satisfies the marginal risk portion of the nominal risk standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We propose that we would require that this percentage exceed the required marginal risk percentage regardless of the amount by which actual expenditures exceeded expected expenditures. APM arrangements with less than 30 percent marginal risk would not meet the nominal risk standard. We believe that meaningful risk arrangements can be designed with marginal risk rates of greater than 30 percent. Any marginal risk below 30 percent creates scenarios in which the total risk could be very high, but the average or likely risk for an APM Entity would actually be very low. We also propose that the payment required by the APM could be smaller when actual expenditures exceed expected expenditures by enough to trigger a payment greater than or equal to the total risk amount required under the nominal risk standard (as specified in Table 28). This is essentially an exception to the marginal risk requirement so that the standard does not effectively require APMs to incorporate total risk greater than the amount required by the total risk portion of the standard.

An example of marginal risk is the sharing rate in the Shared Savings Program. For instance, an ACO in Track 2 or Track 3 of the Shared Savings Program that has a sharing rate, or marginal risk, of 50 percent and exceeds its benchmark (expected expenditures) by $1 million would be liable for $500,000 of those losses. The inclusion of a marginal risk standard is intended to focus on maintaining a more than nominal level of average or likely risk under an Advanced APM. For instance, a APM with a large (for example, 20 percent of benchmark) total potential risk could have a very small (for example, 10 percent) sharing rate as its marginal risk, which substantially mitigates the amount of loss the APM Entity would reasonably expect to incur. We believe that including marginal risk in the Advanced APM financial risk criterion clarifies for APM Entities and eligible clinicians the type of risk they must bear should they pursue becoming QPs. Focusing on marginal risk in the proposed criterion for Other Payer Advanced APMs in section II.F.7.b.(6) of this preamble additionally acts as a guard against gaming through strategic development of risk arrangements with very low marginal risk.

We propose a maximum allowable "minimum loss rate" (MLR) of 4 percent in which the payment required by the APM could be smaller than the nominal amount standard would otherwise require when actual expenditures exceed expected expenditures by less than 4 percent; this exception accommodates APMs that include zero risk with respect to small losses but otherwise satisfy the marginal risk standard. If actual expenditures exceed expected expenditures by an amount exceeding the MLR, then all excess expenditures (including excess expenditures within the MLR) would be subject to the marginal risk requirements. For example, ACOs participating in performance-based risk arrangements under Tracks 2 and 3 of the Shared Savings Program are permitted to choose their own minimum savings rate (MSR) and MLR as long as they are symmetrical. If losses do not exceed the chosen MLR, the ACO is not held responsible for losses. If the ACO has a very large MLR, there may be little to no risk with respect to losses below a certain percentage of the benchmark. Therefore, we believe that proposing a maximum allowable MLR is appropriate. We recognize that there may be instances where an APM can satisfy the marginal risk portion of the nominal risk standard even with a high MLR. Therefore, we also propose a process through which CMS could determine that a risk arrangement with an MLR higher than 4 percent could meet the nominal amount standard, provided that the other portions of the nominal risk standard are met. In determining whether such an exception would be appropriate, CMS would consider: (1) Whether the size of the attributed patient population is small; (2) whether the relative magnitude of expenditures assessed under the APM is particularly small; and (3) in the case of a test of limited size and scope, whether the difference between actual expenditures and expected expenditures would not be statistically significant even when actual expenditures are 4 percent above expected expenditures. We note that CMS would grant such exceptions rarely, and CMS would expect APMs considered for such exceptions to demonstrate that a sufficient number of APM Entities are likely to incur losses in excess of the higher MLR. In other words, the potential for financial losses based on statistically significant expenditures in excess of the benchmark must remain meaningful for participants.

To determine whether an APM satisfies the total risk portion of the nominal risk standard, we would identify the maximum potential payment an APM Entity could be required to make as a percentage of expected expenditures under the APM. If that percentage exceeded the required total risk percentage, then the model would satisfy the total risk portion of the nominal amount standard.

In evaluating both the total and marginal risk portions of the nominal amount standard, we would not include any payments the APM Entity or its eligible clinicians would make to CMS under the APM if actual expenditures exactly matched expected expenditures. In other words, payments made to CMS outside the risk arrangement related to expenditures would not count toward the nominal risk standard. This requirement ensures that perfunctory or pre-determined payments do not supersede incentives for improving efficiency. For example, an APM that simply requires an APM Entity to make a payment equal to 5 percent of the APM benchmark at the end of the year, regardless of actual expenditure performance, would not satisfy the nominal amount standard.

We believe that this approach to measuring the amount of risk flexibly accommodates a wide variety of risk structures, including APMs in which marginal risk varies with the amount of losses. For example, an APM could have a sharing rate of 75 percent for expenditure amounts that exceed the benchmark by up to 2 percent and a sharing rate of 50 percent for expenditure amounts that exceed the benchmark by 2 percent or more. Because the smallest sharing rate is 50 percent, the marginal risk rate exceeds 30 percent at all levels of expenditures, so the model satisfies the marginal risk portion of the nominal amount standard. Because this hypothetical APM does not have MLR or stop loss provisions, it satisfies the total risk and MLR portions of the nominal amount standard.

In particular, the financial risk an Advanced APM Entity would bear under an Advanced APM need not take a shared savings structure in which the financial risk increases smoothly based on the amount by which an Advanced APM Entity's actual expenditures exceed expected expenditures. An example of a risk arrangement being based on shared savings is Tracks 2 and 3 of the Shared Savings Program, where the greater the losses in relation to the expenditure benchmark, the greater the potential amount of shared losses an ACO would be required to repay CMS. On the other hand, an Advanced APM could require APM Entities to pay a penalty based on expenditure targets, regardless of the degree to which the APM Entity actually exceeded those expenditure targets, provided that the payments are otherwise structured in a way that satisfies both the marginal and total risk requirements under the nominal amount standard.

We seek comment on appropriate levels for the allowable minimum loss rate and the parameters we should consider when determining whether a risk arrangement should warrant an exception from the minimum loss rate portion of the nominal amount standard.

Table 28 summarizes the generally applicable nominal amount standard. Tables 29 and 30 provide examples of types of risk arrangements that would and would not meet the financial risk criterion. The examples are divided between shared savings-style arrangements in which marginal risk is a component and non-shared savings arrangements.

Figures C and D illustrate types of payment arrangements would meet the nominal amount standard. Figure C represents the minimum nominal amount standard, so any APM in which the risk for required payments would be on or above the line would satisfy the nominal amount standard. Figure D represents an example of a risk arrangement that would exceed the nominal amount standard.

We seek comment on the Advanced APM nominal amount standard. In particular, we seek comment on whether the Advanced APM benchmark or the Advanced APM Entity revenue is a more appropriate basis for assessing total risk and on the proposed amounts of total potential risk, marginal risk, and maximum allowable minimum loss rate. In particular, we seek comment on whether 30 percent is a sufficient level of marginal risk to be considered "more than nominal." We also seek comment on whether CMS could adopt a meaningful standard that only includes total and marginal risk without the minimum loss rate component. Finally, we seek comment on a tiered nominal risk structure in which different levels of marginal risk could be paired with different levels of total risk.

In commenting on possible alternatives, we encourage commenters to refer to the policy principles articulated in section II.F.1 and to consider the extent to which their proposed alternatives would be more or less consistent with those principles.

FIGURE C: Amount APM Entity Must Owe to Meet the Nominal Amount Standard (30% marginal risk rate, 4% minimum loss rate, and 4% total risk)

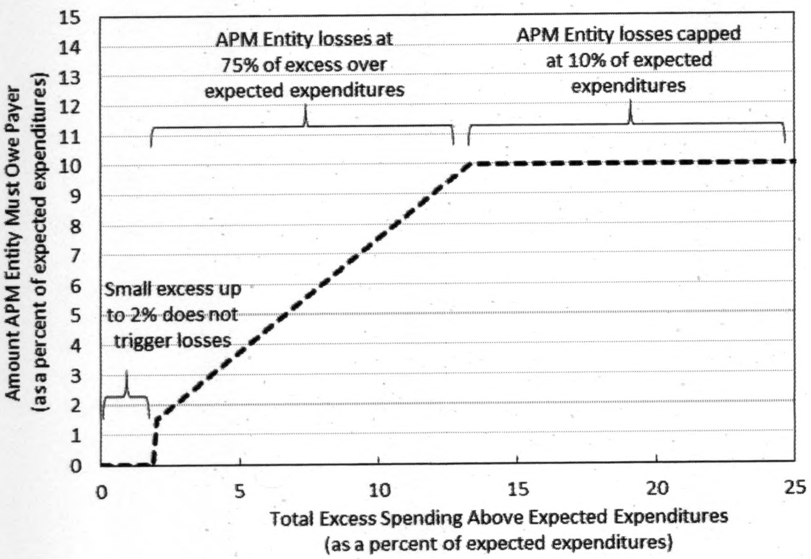


FIGURE D: Example of Risk Arrangement that would meet the Nominal Amount Standard (75% marginal risk rate, 2% minimum loss rate, 10% total risk, and non-episode payment model)

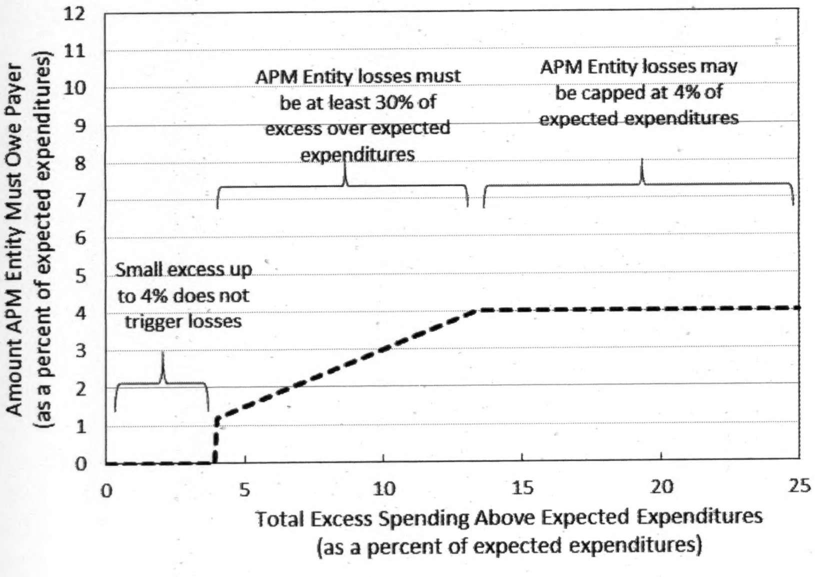


TABLE 28: Amounts of Risk Sufficient to Meet the Nominal Amount Standard

Marginal Risk	Maximum Potential Risk Must be equal to or greater than the following values:
<30%	N/A
30-100% of spending in excess of expected expenditures	4% of expected expenditures

TABLE 29: Examples of Shared Savings Risk Arrangements

	Benchmark	Actual	Marginal Risk (sharing rate)	Stop Loss (maximum amount at risk)	Amount owed	Is Financial Risk Criterion Met?
Example 1	$1,000,000	$1,100,000	50%	15%	$50,000	Yes
Example 2	$1,000,000	$1,100,000	60%	10%	$60,000	Yes
Example 3	$1,000,000	$1,100,000	40%	3%	$30,000	No
Example 4	$1,000,000	$1,100,000	100%	5%	$50,000	Yes
Example 5	$1,000,000	$1,100,000	25%	10%	$25,000	No

TABLE 30: Examples of Risk in Non-Shared Savings Arrangements in 2017

	Risk Arrangement	Performance Standard	Maximum Potential Loss	Is Criterion Met?
Example 1	Percent of FFS payments withheld and paid in lump sum if performance standard is met.	Quality measures	6% withheld	No
Example 2	Percent discount of FFS payments in subsequent year if performance standard is not met.	Expenditures more than 2 percent above expected expenditures	5% reduction	Yes
Example 3	Percent discount of FFS payments with lump sum payment of the difference to APM Entity.	None	10% reduction in FFS payments paid as a lump sum	No

(b) Medical Home Model Standard

We propose that for Medical Home Models, the total annual amount that an Advanced APM Entity potentially owes CMS or foregoes under the Medical Home Model must be at least the following amounts in a given performance year:

- In 2017, 2.5 percent of the APM Entity's total Medicare Parts A and B revenue;
- In 2018, 3 percent of the APM Entity's total Medicare Parts A and B revenue.
- In 2019, 4 percent of the APM Entity's total Medicare Parts A and B revenue.
- In 2020 and later, 5 percent of the APM Entity's total Medicare Parts A and B revenue.

TABLE 31: Examples of Medical Home Model Non-Shared Savings Risk Arrangements in 2017

Example	Medicare Revenue	Maximum Potential Loss	Risk as Percent of Revenue	Is Criterion Met?
Example 1	$1,000,000	Reduction of per beneficiary per month care management fees equal to $30,000 annually.	3%	Yes
Example 2	$1,000,000	Repayment of $50,000 quality performance bonus	5%	Yes
Example 3	$1,000,000	Failure to achieve $25,000 quality bonus	2%	No

We believe the statute's explicit discussion of medical homes gives us unique latitude to separately set financial risk and nominal amount standards for Medical Home Models that fall below an amount we consider sufficient to be "more than nominal" in the context of other types of APMs. We also believe that the meaning of the term "nominal" depends on the situation in which it is applied, so we believe it is appropriate to consider the characteristics of the medical home class of APM Entities in setting the nominal amount standard for Medical Home Models. As we noted in discussing the financial risk standard, few medical homes have had experience with financial risk, and many would be financially unable to provide sufficient care or even remain a viable business in the event of substantial disruptions in revenue. As such, we believe we should base the nominal amount standard on the APM Entity's total Medicare Parts A and B revenues and also not include a potentially excessive level of risk for such entities in the first year of the program. Thus, our proposal sets forth a gradually increasing but achievable long-term amount of risk that would apply in subsequent years. In general, we believe that this scheme allows Medical Home Models to craft incentive designs that allow medical homes to succeed through care transformation and the provision of high-value care while not threatening the ability of small practices to function.

Some benchmarks are based on total cost of care, and, as discussed with respect to the generally applicable nominal amount standard, we generally believe that the APM benchmark or target price is the appropriate basis for evaluating the nominal amount standard. However, we note that, for a small practice, the benchmark can be an amount that is significantly greater than the practice's revenue from all payment sources. Thus, basing the Medical Home Model nominal amount standard on percentage of risk in relation to a total cost of care benchmark would mean that certain types of entities would be required to bear greater total risk in relation to their revenues than other entities, which we believe would be undesirable in light of the special characteristics of Medical Home Models. On the other hand, most APMs base risk on the benchmark instead of revenue, and using revenue as the basis for determining the nominal risk standard could cause the APM Entity's eligibility to vary from year to year based on changes in an APM entity's revenue despite the core risk arrangement remaining unchanged.

For the Medical Home Model nominal amount standard, we seek additional comment on the length of the proposed multi-year "ramp up period" and the magnitude of the total risk amounts during such a period. We also seek comment on the potential addition of a marginal risk amount to the extent applicable and on whether the Advanced APM benchmark or Advanced APM Entity revenue is the most appropriate standard for measuring total risk.

In commenting on possible alternatives, we encourage commenters to refer to the policy principles articulated in section II.F.1 and to consider the extent to which their proposed alternatives would be more or less consistent with those principles.

(5) Capitation

We propose that full capitation risk arrangements would meet the Advanced APM financial risk criterion. We propose that, for purposes of this rulemaking, a capitation risk arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made to an APM Entity for all items and services furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. We also would like to reiterate that—in line with statute—Medicare Advantage and other private plans paid to act as insurers on the Medicare program's behalf are not Advanced APMs.

We believe that capitation risk arrangements, as defined here, involve full risk for the population of beneficiaries covered by the arrangement, recognizing that it might require no services whatsoever or could require exponentially more services than were expected in calculating the capitation rate. The APM Entity bears the full downside and upside risk in this regard. Thus, we believe capitation arrangements inherently require an APM Entity to bear financial risk for monetary losses in excess of a nominal amount. We propose that, where payment is made to participating entities in a APM using a capitation risk arrangement, the APM and participating entities would meet the criterion under section 1833(z)(3)(D)(ii)(I) of the Act.

In implementing this proposed policy, it is important to distinguish capitation as a risk arrangement from capitation as only a cash flow mechanism. A capitation risk arrangement adheres to the idea of a global budget for all items and services to a population of beneficiaries during a fixed period of time. Cash flow mechanisms that make payments in predetermined amounts that are later reconciled or adjusted based on actual services are not necessarily a full risk arrangement. For example, an APM Entity has a capitation arrangement under an APM that pays $1,000 per beneficiary per month for a population of 100 beneficiaries, totaling $1.2 million per year. If expenditures for services actually furnished to these beneficiaries would have totaled $1.3 million if paid on a fee-for-service basis, a payment mechanism without risk might make a reconciliation payment of $100,000 to the entity. In that case, the APM Entity is not bearing any financial risk for monetary losses under the APM. If there is partial reconciliation, the arrangement would not meet the proposed capitation risk arrangement definition but still may meet the financial risk and nominal amount standards through the assessments described in this section above. In contrast, if this arrangement is a capitation risk arrangement, there would be zero reconciliation for those losses. Under our proposal, we would categorically accept that a capitation risk arrangement under an APM would meet the Advanced APM financial risk criterion.

We seek comment on our proposal for acceptance of capitation risk arrangements and on our proposed definition of a capitation risk arrangement. We also seek comment on other types of arrangements that may be suitable for such treatment for purposes of this financial risk criterion. Finally, we seek comment on potential limits or qualifications to the capitation standard in order to prevent potential abuse or incentives that are not consistent with the provision of high value care.

(6) Medical Home Expanded Under Section 1115A(c) of the Act

Section 1833(z)(3)(D)(ii)(II) of the Act states that an Advanced APM must either meet the financial risk criterion or be a Medical Home Model expanded under section 1115A(c) of the Act. We will refer to the latter criterion as the expanded Medical Home Model criterion. We propose that a Medical Home Model that has been expanded under section 1115A(c) of the Act would meet the expanded Medical Home Model criterion and thus would not need to meet the Advanced APM financial risk criterion as described above. Under this this proposal, an APM would have to both be determined to be a Medical Home Model as defined in this rulemaking and in fact be expanded using the authority under section 1115A(c) of the Act. Such expansion is contingent upon whether, for an APM tested under section 1115A(b) of the Act:

- The Secretary determines that such expansions is expected to reduce spending under the applicable title without reducing the quality of care; or improve the quality of patient care without increasing spending;
- CMS' Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending under the applicable titles; and
- The Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

We note that the expanded Medical Home Model criterion cannot met unless a Medical Home Model has been expanded under section 1115A(c). Merely satisfying expansion criteria would not be sufficient to meet this Advanced APM criterion. This expanded Medical Home Model criterion is directly related to a similar criterion addressed in this proposed rule for Medicaid Medical Home Models, which addresses how such APMs can meet the Other Payer Advanced APM financial risk criterion by having criteria comparable to an expanded Medical Home Model. We request comments on the proposed requirements for this and all proposed Advanced APM criteria.

(7) Application of Criteria to Current and Recently Announced APMs

Using the Advanced APM criteria proposed in sections II.F.4.b.1–6 of this preamble, we have identified the current APMs that we anticipate would be Advanced APMs for the first QP Performance Period. We note that since no CMS Medical Home APMs have been expanded under section 1115A(c) of the Act, we have not included this criterion in the table.

The information presented in Table 32 is based on the preliminary application of proposed Advanced APM criteria in this preamble and does not preclude any changes to the list based on: (1) Any changes made to the proposed criteria in the publication of the final rule in response to public comments; (2) any modifications to the design of current APMs; or (3) any new APMs announced between publication of this proposed rule and the beginning of the first QP Performance Period. Consistent with our proposal in section II.F.4.a, we propose to post an official determination of which APMs would meet the final Advanced APM criteria prior to the beginning of the first QP Performance Period and update that list in accordingly.

We note that the Comprehensive Care for Joint Replacement (CJR) model does not meet the Advanced APM criteria proposed in sections II.F.4.b.1–6 of this preamble. We seek comment on how we might change the design of CJR through future rulemaking to make it an Advanced APM, and we seek comment on how to include eligible clinicians in CJR for purposes of the QP determination as described in section II.F.5.

TABLE 32: APM List Based on Proposed Criteria

APM and Abbreviation	Qualifies as a MIPS APM for APM Scoring Standard under II.E.3.h	Medical Home Model	Use of CEHRT Criterion	Quality Measures Criterion	Financial Risk Criterion	Advanced APM
Bundled Payment for Care Improvement Model 2 (BPCI)	NO	NO	NO	NO	YES	NO
Bundled Payment for Care Improvement Model 3 (BPCI)	NO	NO	NO	NO	YES	NO
Bundled Payment for Care Improvement Model 4 (BPCI)	NO	NO	NO	NO	YES	NO
Comprehensive Care for Joint Replacement (CJR)	NO	NO	NO	YES	YES	NO
Comprehensive ESRD Care (CEC) (LDO arrangement)	YES	NO	YES	YES	YES	YES
Comprehensive ESRD Care (CEC) (non- LDO arrangement)	YES	NO	YES	YES	NO	NO
Comprehensive Primary Care Plus (CPC +)	YES	YES	YES	YES	YES	YES
Frontier Community Health Integration Program (FCHIP)	NO	NO	NO	NO	NO	NO
Health Plan Innovation (HPI) - Medicare Advantage Value-Based Insurance Design Model (MA VBID)	NO	NO	NO	NO	NO	NO
Health Plan Innovation (HPI)- Part D Enhanced Medication Therapy Management Model	NO	NO	NO	NO	NO	NO
Home Health Value-Based Purchasing Model (HH-VBP)	NO	NO	NO	NO	NO	NO
Independence at Home Demonstration (IAH)	NO	YES	NO	YES	NO	NO
Initiative to Reduce Preventable Hospitalizations Among Nursing Facility Residents - Phase 2	NO	NO	NO	NO	NO	NO
Intravenous Immune Globulin (IVIG) Demonstration	NO	NO	NO	NO	NO	NO
Maryland All-Payer Hospital Model (MM)	NO	NO	NO	NO	NO	NO
Medicare Part B Drugs	NO	NO	NO	NO	NO	NO

APM and Abbreviation	Qualifies as a MIPS APM for APM Scoring Standard under II.E.3.h	Medical Home Model	Use of CEHRT Criterion	Quality Measures Criterion	Financial Risk Criterion	Advanced APM
Payment Model						
Medicare Care Choices Model (MCCM)	NO	NO	NO	NO	NO	NO
Medicare Shared Savings Program - Track 1 (MSSP)	YES	NO	YES	YES	NO	NO
Medicare Shared Savings Program - Track 2 (MSSP)	YES	NO	YES	YES	YES	YES
Medicare Shared Savings Program - Track 3 (MSSP)	YES	NO	YES	YES	YES	YES
Million Hearts: Cardiovascular Risk Reduction Model (MH CVDRR)	NO	NO	NO	NO	NO	NO
Next Generation ACO Model	YES	NO	YES	YES	YES	YES
Oncology Care Model (OCM) one-sided risk arrangement	YES	NO	YES	YES	NO	NO
Oncology Care Model (OCM) two-sided risk arrangement	YES	NO	YES	YES	YES	YES

5. Qualifying APM Participant (QP) and Partial QP Determination

The QP determination process is specified under section 1833(z)(2) of the Act, in which QPs are defined as those eligible clinicians who meet the specified threshold(s).

In this section, we propose a process for determining which eligible clinicians would be QPs or Partial QPs for a given payment year through their participation in Advanced APMs during a corresponding QP Performance Period. Per sections 1833(z)(2) and 1848(q)(1)(C)(ii)(I) and (II) of the Act, an eligible clinician would become a QP or Partial QP for a payment year if they are determined at the end of the performance period to be eligible clinicians in an Advanced APM Entity that collectively meets the threshold values for participation in an Advanced APM during the corresponding QP Performance Period, and starting in 2021, the threshold values for participation in an Other Payer Advanced APMs as proposed here. Each year, CMS would determine whether an eligible clinician achieved the threshold to become a QP or Partial QP during the corresponding QP Performance Period. CMS would make this assessment independent of QP or Partial QP determinations made in previous years and accounting for Advanced APMs that begin or end on timeframes that do not align precisely with the QP Performance Period. The following would apply to an eligible clinician whom CMS determines to be a QP for a particular year:

- For payment years 2019–2024, the QP will receive a lump sum payment equal to 5 percent of the estimated aggregate payment amounts for Medicare Part B covered professional services for the prior year, as described in section II.F.8 of this preamble;
- The QP will be excluded from MIPS payment adjustments, as described in section II.E.3 of this preamble; and
- For payment years 2026 and later, payment rates under the Medicare physician fee schedule for services furnished by the eligible clinician will be updated by the 0.75 percent qualifying APM conversion factor as specified in sections 1848(d)(1)(A) and (d)(20) of the Act.

Through the APM Entity group determination described in section II.F.5.b of this preamble, CMS would identify eligible clinicians who do not meet the QP threshold but reach the Partial QP threshold for a year to be Partial QPs. Partial QPs would not be eligible for the 5 percent APM Incentive Payment for years from 2019 through 2024 or, beginning for 2026, the qualifying APM conversion factor. However, as described below, Partial QPs would have an opportunity to decide whether they wish to be subject to a MIPS payment adjustment, which could be positive or negative.

The statute requires that we use two options to determine whether an eligible clinician is a QP or Partial QPs for a payment year—one is the Medicare Option and, beginning in 2021, the other is the All-Payer Combination Option. While these are the terms based on statutory language that we have chosen to use for the purposes of describing the process by which we can calculate an eligible clinician's Threshold Score, we note that the use of the word "option" does not imply that an eligible clinician will have the ability to choose between the two. We further outline in this section our proposed process by which we will assess eligible clinicians under both options (beginning in 2021) to the extent that sufficient data is submitted to CMS.

The Medicare Option, described in this section, focuses on participation in Advanced APMs, and CMS would make determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an Advanced APM Entity. The Medicare Option is the only option available for QP determinations during the first two years of this program (payment years 2019–2020). The All-Payer Combination Option, described in section II.F.7 of this preamble, is applicable beginning in the third payment year (2021) and would allow CMS to make determinations based on participation in both Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option would not replace or supersede the Medicare Option; instead it would allow eligible clinicians to become QPs by meeting a relatively lower threshold based on Medicare Part B covered professional services through Advanced APMs and an overall threshold based on services through both Advanced APMs and Other Payer Advanced APMs. With our proposals for the QP Threshold Score methodologies described in this section, we generally interpret payments "through" an Advanced APM Entity to mean payments made by CMS for services furnished to attributed beneficiaries, who are the beneficiaries for whose costs and quality of care an Advanced APM Entity is responsible under the Advanced APM. Under section 1848(q)(1)(C)(iii) of the Act, the calculations used for Partial QP determinations are the same, but the threshold percentages to be a Partial QP for each year are lower than those required to be a QP.

The QP and Partial QP Thresholds under the Medicare Option are shown in Tables 33 and 35. The QP and Partial QP Threshold values under the All-Payer Combination Option are shown in Tables 34 and 36. CMS will determine an eligible clinician's QP status for a payment year by calculating an eligible clinician's Threshold Score, and comparing the eligible clinician's Threshold Score (either based on payment amounts or patient counts) to the relevant QP Threshold or Partial QP Threshold. In addition, we discuss our proposal to make QP determinations at a group level based on an entire Advanced APM Entity in section II.F.5.b of this preamble.

According to section 1833(z)(2)(D) of the Act, the Secretary may base the determination of whether an eligible clinician is a QP or a Partial QP by using counts of patients in lieu of using payment amounts and using the same or similar percentage criteria as those used for the payment amount method, as the Secretary determines is appropriate. For QP and Partial QP determinations using patient count calculations, we propose to use the percentage values displayed in Tables 35 and 36. The purpose of the proposed design of the Medicare patient count method is to make QP status determinations accessible to entities and individuals who are clearly and significantly engaged in delivering value-based care through participation in Advanced APMs. We also propose that when determining whether to use the payment amounts or patient counts method to calculate the QP threshold status, CMS will use both methods in tandem for each Advanced APM Entity group of eligible clinicians. We further propose that after QP and Partial QP threshold calculations have been completed, we will use the QP threshold method that is more favorable to the Advanced APM Entity group of eligible clinicians.

By performing preliminary analyses using our proposed QP determination methodologies with historical APM data, we found that the proposed QP and Partial QP Patient Count Thresholds are similar in magnitude and trajectory to those specified in the statute for the payment-based calculations. Due to varying attribution and organizational characteristics, we anticipate that using our proposed thresholds, the method—payment amount or patient count—that results in the most favorable QP status will likely vary across different Advanced APMs and Advanced APM Entities. We believe that each eligible clinician should have every opportunity to reach the QP threshold for each year, and do not intend to limit this opportunity by preemptively selecting one method over another.

We seek comment on the proposed QP Patient Count Threshold and Partial QP Patient Count Threshold percentage values for both the Medicare Option and the All-Payer Combination Option, on our proposal to calculate the Threshold Score under the payment amount and patient count methods simultaneously, and on our proposal to use the method that is most favorable to the Advanced APM Entity group of eligible clinicians.

TABLE 33: QP Payment Amount Thresholds – Medicare Option

Medicare Option – Payment Amount Method						
Payment Year	**2019**	**2020**	**2021**	**2022**	**2023**	**2024 and later**
QP Payment Amount Threshold	25%	25%	50%	50%	75%	75%
Partial QP Payment Amount Threshold	20%	20%	40%	40%	50%	50%

TABLE 34: QP Payment Amount Thresholds – All-Payer Combination Option

All-Payer Combination Option – Payment Amount Method										
Payment Year	**2019**	**2020**	**2021**		**2022**		**2023**		**2024 and later**	
QP Payment Amount Threshold	N/A	N/A	50%	25%	50%	25%	75%	25%	75%	25%
Partial QP Payment Amount Threshold	N/A	N/A	40%	20%	40%	20%	50%	20%	50%	20%
			Total	Medicare	Total	Medicare	Total	Medicare	Total	Medicare

TABLE 35: QP Patient Count Thresholds – Medicare Option

Medicare Threshold Option – Patient Count Method						
Payment Year	**2019**	**2020**	**2021**	**2022**	**2023**	**2024 and later**
QP Patient Count Threshold	20%	20%	35%	35%	50%	50%
Partial QP Patient Count Threshold	10%	10%	25%	25%	35%	35%

TABLE 36: QP Patient Count Thresholds – All-Payer Combination Option

All-Payer Combination Option – Patient Count Method										
Payment Year	**2019**	**2020**	**2021**		**2022**		**2023**		**2024 and later**	
QP Patient Count Threshold	N/A	N/A	35%	20%	35%	20%	50%	20%	50%	20%
Partial QP Patient Count Threshold	N/A	N/A	25%	10%	25%	10%	35%	10%	35%	10%
			Total	Medicare	Total	Medicare	Total	Medicare	Total	Medicare

We propose that, beginning with payment year 2021, CMS will conduct the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option. We propose to apply the All-Payer Combination Option only to an Advanced APM Entity group of eligible clinicians or eligible clinicians who do not meet either the QP Payment Amount or Patient Count Threshold under the Medicare Option but who do meet the lower Medicare threshold for the All-Payer Combination Option. This process is illustrated in Figures E and F, which show that the first assessment is whether the Medicare QP Threshold has been met under either the Medicare Option or the All-Payer Combination Option.

Because the Medicare Option (either based on payment amounts or patient counts) is also part of the All-Payer Combination Option, and because all eligible clinicians must reach at least a minimum Medicare Threshold Score through Advanced APMs to be QPs, we believe that this sequential approach streamlines the analytic and operational requirements to make QP determinations under the All-Payer Combination Option. Figure E illustrates the proposed process for making QP determinations under the Medicare Option for 2019 and 2020. Figure F illustrates the process proposed for making QP determinations under both the Medicare and All-Payer Combination Options for payment years 2021–2024. Figure G provides an example of the proposed process for making QP determinations in payment years 2023–2024. Figures E, F, and G only discuss the payment amount method, but a similar process would apply for the patient count method.

FIGURE E: QP Determination Tree, Payment Years 2019-2020

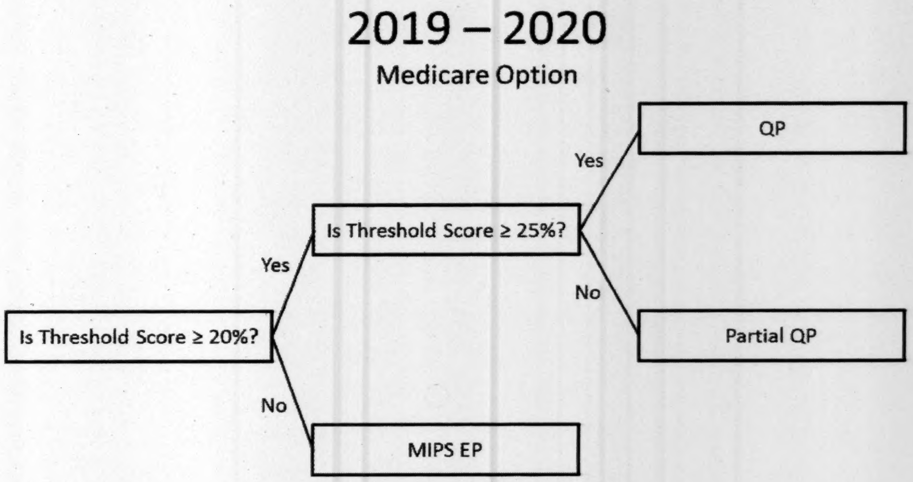

2019 – 2020
Medicare Option
Is Threshold Score ≥ 20%?
Yes
Is Threshold Score ≥ 25%?
Yes
QP
No
Partial QP
No
MIPS EP

FIGURE F: QP Determination Tree, Payment Years 2021-2022

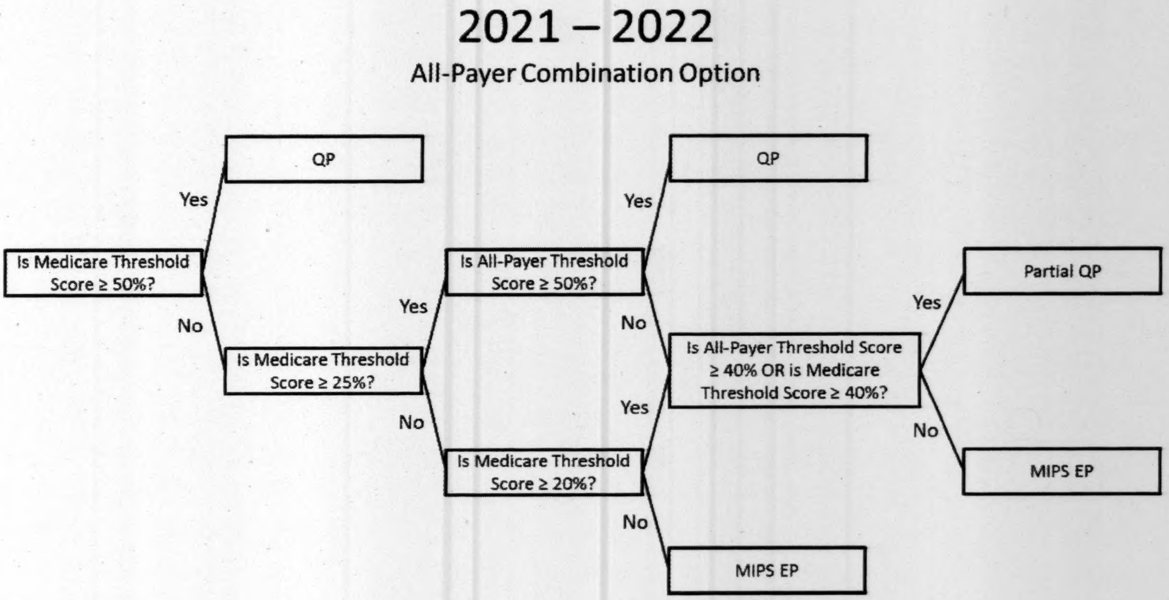
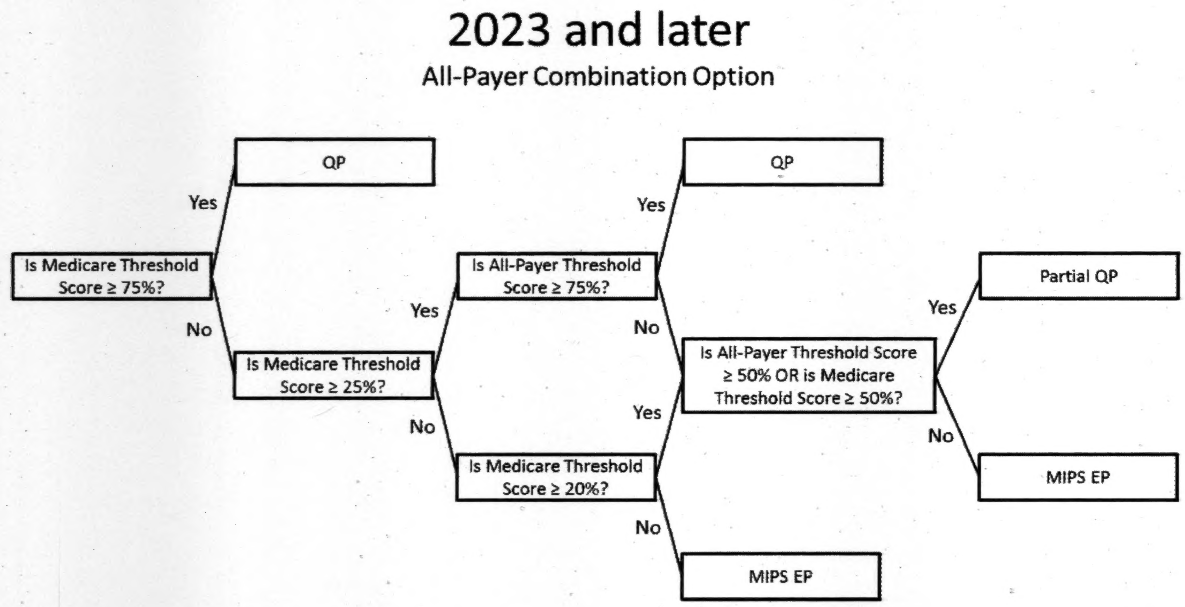

2021 – 2022
All-Payer Combination Option
Is Medicare Threshold Score ≥ 50%?
Yes
QP
No
Is Medicare Threshold Score ≥ 25%?
Yes
Is All-Payer Threshold Score ≥ 50%?
Yes
QP
No
Is All-Payer Threshold Score ≥ 40% OR is Medicare Threshold Score ≥ 40%?
Yes
Partial QP
No
MIPS EP
No
Is Medicare Threshold Score ≥ 20%?
Yes
No
MIPS EP

FIGURE G: QP Determination Tree, Payment Years 2023 and Later


2023 and later
All-Payer Combination Option
Is Medicare Threshold Score ≥ 75%?
Yes
QP
No
Is Medicare Threshold Score ≥ 25%?
Yes
Is All-Payer Threshold Score ≥ 75%?
Yes
QP
No
Is All-Payer Threshold Score ≥ 50% OR is Medicare Threshold Score ≥ 50%?
Yes
Partial QP
No
MIPS EP
No
Is Medicare Threshold Score ≥ 20%?
Yes
No
MIPS EP

a. QP Performance Period

According to section 1833(z)(2) of the Act, we are required to determine QP and Partial QP status based on payment amounts (or patient counts) during the most recent period for which data are available (which may be less than a year). We propose that the QP Performance Period is the full calendar year that aligns with the MIPS performance period (for instance, 2017 would be the QP Performance Period for the 2019 payment year). We believe that having a QP Performance Period parallel with the proposed MIPS performance period offers will reduce operational complexity and gives CMS the opportunity to clearly communicate an eligible clinician's status in this program throughout the process. We also believe that having a QP Performance Period that concludes one year and one day before the payment year enables CMS to provide all eligible clinicians participating in Advanced APMs the best opportunity to monitor their performance through the Advanced APM and make the most informed decisions regarding their decision whether to not to be subject to MIPS in the event that they become a Partial QP. We seek comment on this proposal and any alternative QP Performance Period timeframes that would both enable meaningful QP assessment and ensure operational alignment with MIPS.

FIGURE H: Proposed QP Performance Period

Proposed QP Timeline

2017	2018	2019
		QP Performance Period 3
	QP Performance Period 2	Incentive Payment Base Period 2
QP Performance Period 1	Incentive Payment Base Period 1	QP Incentive Payment 1

Proposed MIPS Timeline

2017	2018	2019
		MIPS Performance Period 3
	MIPS Performance Period 2	MIPS Submission and Analysis 2
MIPS Performance Period 1	MIPS Submission and Analysis 1	MIPS Payment Adjustments 1

b. Group Determination and Lists

(1) Group Determination

The statute consistently refers to an eligible clinician throughout section 1833(z) of the Act and clearly identifies that the QP determinations are to be made for an eligible clinician. In section 1833(z)(3)(B) of the Act, the definition of an eligible clinician includes a group of such professionals. We received several comments to our MIPS and APMs RFI recommending that CMS make QP determinations at a group level and indicating a preference for entity cohesion over a highly precise analysis for individual eligible clinicians. Commenters stated a number of reasons why they recommended that QP determinations should be made at the group level. These reasons included promoting administrative simplicity, the need to foster collaboration among group members (instead of promoting barriers), and the fact that while many beneficiaries are attributed to an APM Entity based on the services rendered by one eligible clinician, many of the eligible clinicians participating in the APM Entity may play a role in the actual diagnosis, treatment, and management of many beneficiaries in the APM Entity population. Each of these individual eligible clinicians could potentially view themselves as being instrumental in providing quality care to the beneficiary that is in line with the objectives of the APM, regardless of whether their individual services are counted towards APM-specific attribution methods. A few commenters indicated that the Advanced APM Entities themselves should determine whether individual eligible clinicians meet the annual threshold to become a QP.

An Advanced APM Entity faces the risks and rewards of participation in an Advanced APM as a single unit, and is responsible for performance metrics that are aggregated to the level of that entity. This policy is also based on the premise that positive change occurs when entire organizations commit to participating in an Advanced APM and focusing on its cost and quality goals as a whole. It also mitigates situations in which individual eligible clinicians who practice together in an Advanced APM Entity receive different QP determinations and thus are treated differently for purposes of APM Incentive Payments, MIPS payment adjustments, and eventually, differential fee schedule updates under the PFS. We believe that such discrepancies could potentially lead to confusion and lack of cohesion among eligible clinicians and Advanced APM Entities and place additional burdens on eligible clinicians and organizations to track these differences. Additionally, we wish to avoid any additional burden, confusion, and operational difficulties for both eligible clinicians and CMS that would result from allowing eligible clinicians or Advanced APM Entities to elect whether to be assessed at the Advanced APM Entity level. We believe that a simple, overarching rule is preferable to adding extra variables to the already complex processes under this program.

We understand that, as with any group assessment, there will be some situations in which individual Threshold Scores would differ from group Threshold Scores if assessed separately. This could lead to some eligible clinicians becoming QPs when they would not have met the QP Threshold individually (a "free-rider" scenario) or, conversely, some eligible clinicians not becoming QPs within an Advanced APM Entity when they might have qualified individually (a dilution scenario). We believe that through the methodology we propose for QP determination in this proposed rule, the magnitude of such discrepancies will be relatively small compared to the value of maintaining Advanced APM Entity cohesion.

We propose, except in the specific situations discussed below in this section, to make the QP determination at a group level. As a result, the QP determination for the group would apply to all the individual eligible Clinicians who are identified as part of an Advanced APM Entity. If that eligible Clinician group's collective Threshold Score meets the relevant QP threshold, all eligible Clinicians in that group would receive the same QP determination for the relevant year. The QP determination calculations described in this proposed rule would be aggregated using data for all eligible clinicians participating in the Advanced APM Entity during the QP Performance Period.

In some cases, the list of eligible clinicians who will be grouped together for purposes of the QP determination may include eligible clinicians who have relationships with the Advanced APM Entity but no relationship with each other. We believe this is appropriate for purposes of the QP determination because it support the Advanced APM Entity as the coordinator of its participating eligible clinicians to contribute to its success and promotes eligible clinician coordination when appropriate to further the success of the Advanced APM Entity.

(2) Groups Used for QP Determination

We propose that the group of eligible clinicians would consist of all the eligible clinicians identified as participants in an Advanced APM Entity during the QP Performance Period on a Participation List provided to CMS, with one exception for Advanced APMs whose participants are not eligible clinicians. We propose to define participant for the purposes of participation in an APM as an entity participating in an APM under an agreement with CMS or statute or regulation that may either include eligible clinicians or be an eligible clinician and that is directly tied to beneficiary attribution, quality measurement or cost measurement under the APM. This definition encapsulates those entities and eligible clinicians under an APM who have roles of central importance to performance under the APM. We propose that the Participation List for each Advanced APM Entity would be compiled from CMS-maintained lists that will be used to identify each eligible clinician by a unique TIN/NPI combination attached to the identifier of the Advanced APM Entity. Therefore, an eligible clinician must be officially identified using an Advanced APM Entity's Participation List to be part of the QP determination for that group.

In APMs, the APM Entity that has an agreement with CMS or is identified as such under statute or regulation is considered a participant in the APM. Some APMs have eligible clinicians under the APM Entity who are also under our definition considered participants in the Advanced APM Entity. For example, in an APM like the Comprehensive Primary Care Initiative with physician group practices as participants, the APM Entity, the Practice, may have a Participation List it provides to CMS that can be used to identify each eligible clinician participant participating in the APM through that APM Entity by a unique TIN/NPI combination attached to the identifier of the APM Entity. As stated above, we propose to include of all the eligible clinicians identified using a Participation List as participants in an Advanced APM Entity during the QP Performance Period for purposes of the QP determination.

In certain APMs, a Participation List may not include any eligible clinicians. For example, in an APM where all APM Entities are hospitals, the APM Entity will not have eligible clinicians identified by a unique TIN/NPI combination attached to the identifier of the Advanced APM Entity on a

Participation List because there will not be eligible clinicians who are participants under the APM Entity. An Advanced APM Entity may have a list of entities, including eligible clinicians, who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM, but are not participants and are therefore not on a Participation List. For example, a list of gainsharers under an APM might include eligible clinicians where the Participation List does not.

Where there is a Participation List that can be used to identify eligible clinicians, we propose that it automatically be the list that is considered for the QP Determination. Where there is no Participation List that can be used to identify eligible clinicians, but there is another list of eligible clinicians who have a contractual relationship with the Advanced APM Entity based at least in part on supporting the Advanced APM Entity's quality or cost goals under the Advanced APM (Affiliated Practitioners), we propose to use the list of those eligible clinicians, the Affiliated Practitioner List, for purposes of the QP determination. Where there is both a Participation List and an Affiliated Practitioner List that can be used to identify eligible clinicians under an Advanced APM, we propose only to use the Participation List for purposes of the QP determination. We seek comment on whether to limit the proposed policy to use an Affiliated Practitioner List for the QP Determination to the Medicare payment threshold option, as it may be less likely that Affiliated Practitioners support the Advanced APM Entity as a group in Other Payer Advanced APMs than eligible clinicians on a Participation List.

This proposed policy was developed to capture the group or groups of eligible clinicians who are the most closely associated with the performance of the Advanced APM Entity under an Advanced APM and to recognize their role in supporting the Advanced APM Entity. We believe this policy appropriately considers those eligible clinicians who have the most central role or roles in supporting the Advanced APM Entity's performance under an Advanced APM to be the eligible clinician group for purposes of the QP determination. We believe this policy provides for flexibility in the design of Advanced APMs while providing the APM Incentive Payment to those eligible clinicians who are the most engaged in the Advanced APM. We believe this will promote more robust engagement by eligible clinicians in Advanced APMs, and appropriately incentivize participation in Advanced APMs where eligible clinicians have a less direct relationship with the Advanced APM Entity than eligible clinicians who are on a Participation List. We also believe that although the relationship an Affiliated Practitioner has with an Advanced APM Entity is less direct than an eligible clinician on a Practitioner List, the contractual relationship the Affiliated Practitioner has with the Advanced APM Entity is sufficient for an Affiliated Practitioner can become a QP based on their support of the Advanced APM Entity.

We seek comment on our proposals for defining the eligible clinician group for QP determinations, particularly our proposals to define the eligible clinician group for QP determination as the Participation List, and the exception for Advanced APMs in which there are no eligible clinicians on the Participation List but there are eligible clinicians on an Affiliated Practitioner List. Because there may be Advanced APMs in the future that have multiple lists of Affiliated Practitioners, we plan to propose a policy for such situations in future rulemaking, and we seek comment on approaches for grouping those separate lists for purposes of the QP determination.

(3) Timing of Group Identification for Eligible Clinicians

We propose that we will identify the eligible clinician group for each Advanced APM Entity at a specified point in time for each QP Performance Period. We propose that this point in time assessment will occur on December 31st of each QP Performance Period. We believe that taking a "snapshot" of the participant list on the last day of the proposed QP Performance Period provides the best opportunity to comprehensively assess the eligible clinicians' active participation in an Advanced APM throughout an entire QP Performance Period. Under this proposal, we would use the eligible clinicians identified using the Participant List as the group of eligible clinicians who would be assessed together for the purposes of QP determination. We considered taking the "snapshot" at an earlier point in the QP Performance Period, but we felt that because certain APMs allow for changes in participation (either adding or dropping participants from the APM Entity) during the calendar year, an earlier "snapshot" date would not be the most accurate reflection of active eligible clinician participation in a APM throughout the QP Performance Period. We believe that these proposals maintain cohesiveness for eligible clinicians and Advanced APM Entities and maintain consistency with the participation structure of Advanced APMs.

We seek comment on our proposal to assess each Participation List for each Advanced APM Entity at a specified point in time during the QP Performance Period. We also seek comment on the proposed date of the Participant List assessment, and whether this date should be earlier in the QP Performance Period or should instead be a range of time.

(3) Exception

We propose one exception to making QP determinations at the group level. Some eligible clinicians may participate in multiple Advanced APMs. For instance, an eligible clinician could participate in an ACO under the Shared Saving Program and an episode payment model with another entity, both of which have been determined to be Advanced APM Entities. In such a case, we propose the following:

- Consistent with the general policy proposed above, if one or more of the Advanced APM Entities in which the eligible clinician participates meets the QP threshold, the eligible clinician becomes a QP.
- If none of the Advanced APM Entities in which the eligible clinician participates meet the QP threshold, CMS proposes to assess the eligible clinician individually, using combined information for services associated with that individual's NPI and furnished through all such eligible clinician's Advanced APM Entities during the QP Performance Period. CMS will adjust to assure that services are not double-counted (for example, a surgeon participating in a bundled payments model, in which some of the procedures are performed on patients affiliated with an ACO that the surgeon is also a part of, would only have payments or patients from those procedures count once towards the QP determination).

We believe that this proposal maintains the general simplicity of the Advanced APM Entity-level QP determination while acknowledging individual eligible clinicians who are participating in multiple advanced initiatives that support CMS goals. This also complements the policy described under the All-Payer Combination Option for QP determinations in which an eligible clinician may submit information on participation in Other Payer Advanced APMs in order to be assessed as an individual under that option in the event that the APM Entity or Entities in which the eligible clinician participates do not submit sufficient information.

We seek comment on the proposal to make most QP determinations at the Advanced APM Entity level and our proposals for exceptions to that policy. In particular, we seek comment on the merits of making all determinations at the individual eligible clinician level versus through some alternative grouping methodology. We also seek comment on our proposal to assess an eligible clinician who participates in multiple Advanced APM Entities, and any other potential exceptions to the proposed general policy to make QP determinations at the Advanced APM level.

c. Partial QP Election To Report to MIPS

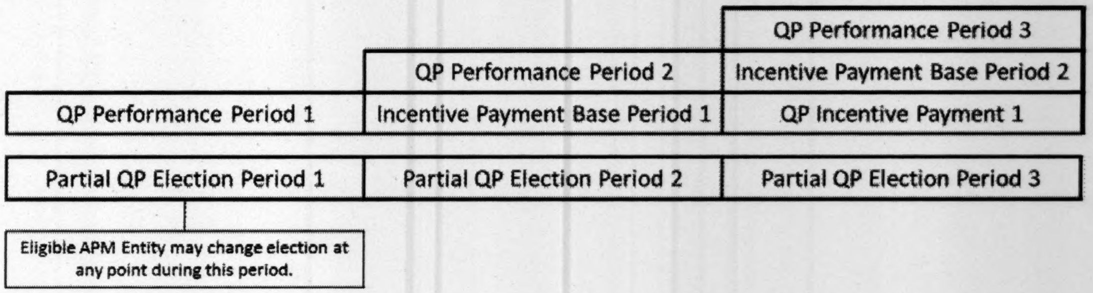
Section 1848(q)(1)(C)(ii)(II) of the Act excludes from the definition of MIPS eligible clinician an eligible clinician who is a Partial QP for a year. However, under section 1848(q)(1)(C)(vii) of the Act, an eligible clinician who is a Partial QP for a year and reports on applicable measures and activities as required under the MIPS is considered to be a MIPS eligible clinician for the year. To carry out these provisions, we propose to require that each Advanced APM Entity must make an election each year on behalf of all of its identified participating eligible clinicians on whether to report under MIPS in the event that the eligible clinicians participating in the Advanced APM Entity are determined as a group to be Partial QPs for a year. We propose that the Advanced APM Entity could change its election for a year at any time during the QP Performance Period, but the election would become permanent at the close of the QP Performance Period. We believe that this is consistent with our proposed general policy to make QP determinations at the Advanced APM Entity level; and with related MIPS policies described in section II.E.3.h of this preamble, under which we propose that each APM Entity would be considered a group for purposes of MIPS reporting. Therefore, we believe that the decision of whether to report and subsequently be subject to MIPS adjustments should also be made at the group level. We seek comment on whether the Advanced APM Entity or each individual eligible clinician should make the Partial QP MIPS reporting election.

As discussed in section II.E.3.h. of this preamble, we recognize that the Shared Savings Program eligible clinicians participate as a complete TIN such that all of the eligible clinician participants in the participant billing TIN participate in the Shared Savings Program. Therefore, we also seek comment on an alternative approach for Shared Savings Program APM Entities in which each individual billing TIN participating in the APM Entity would make the Partial QP election on behalf of its individual eligible clinicians and that election would be applied to all eligible clinicians in that individual billing TIN, as opposed to having the APM Entity (ACO) make the Partial QP election. We would only undertake this alternative paired with determining MIPS CPS for each TIN within an APM Entity (ACO) at the TIN level, an alternative discussed under the APM scoring standard elsewhere in this proposed rule.

Our proposal that Partial QPs may choose whether to report to MIPS has two additional interactions with other proposed policies. First, because we have proposed unique MIPS scoring policies for MIPS eligible clinicians participating in certain APMs, the election by the APM Entity not to report under MIPS is in effect a decision to tell CMS not to score the information submitted by the APM Entity under MIPS. Under our proposal, that decision would be made at the APM Entity level. APM Entities and eligible clinicians would continue to report to their respective APMs as required under the terms of their participation agreements with CMS.

Second, given the proposed timeframe for QP determinations under section II.F.5.a, our proposed treatment of claims run-out, claims adjustments, supplemental service payments, and alternative payment methods for purposes of QP determination (further detailed in section II.F.8 of this preamble), and the and subsequent notification of QP determinations proposed under section II.F.5.d of this preamble, eligible clinicians who become Partial QPs would not receive notification of this status until after the proposed timeframe for the MIPS reporting period will have closed. We do not believe that it would be in the best interest of APM Entities and eligible clinicians, nor would it be operationally feasible, to have APM Entities wait to make a Partial QP election to be included in MIPS until after the close of the MIPS reporting period. Although the information necessary for MIPS reporting would already be prepared in the CMS systems by the time the Partial QP determination is made, a prospective election by the Advanced APM Entity to not be scored under MIPS and receive a MIPS payment adjustment would signal us to not transfer information from our reporting system to the MIPS scoring system in the event of a Partial QP determination, and that any submitted information is not to be used for purposes of a MIPS assessment or payment adjustment. Thus, by choosing not to report under MIPS, those Advanced APM Entities and eligible clinicians determined to be Partial QPs would be exempted from the MIPS payment adjustment for that year. We seek comment on the timing and process for Advanced APM entities to elect whether to be subject to MIPS in the event of a Partial QP determination.

FIGURE I: Partial QP Election Timeframe


QP Performance Period 3
QP Performance Period 2
Incentive Payment Base Period 2
QP Performance Period 1
Incentive Payment Base Period 1
QP Incentive Payment 1
Partial QP Election Period 1
Partial QP Election Period 2
Partial QP Election Period 3
Eligible APM Entity may change election at any point during this period.

d. Notification of QP Determination

We propose to notify both Advanced APM Entities and their participating eligible clinicians of their QP and Partial QP status as soon as CMS has made the determination and performed all necessary validation of the results. Given the proposed timeframe for QP determinations under section II.F.5.a of this preamble and our proposed treatment of claims run-out (further detailed in section II.F.8 of this preamble), we do not anticipate that this notification could be made before the summer of the subsequent year. We propose that this notification would be made directly to the Advanced APM Entity and eligible clinician, and made in combination with a general public notice on the CMS Web site that such determinations have been completed for the applicable QP Performance Period. We propose that this notification would also contain other necessary and useful information, such as what actions, if any, an Advanced APM Entity or eligible clinician may or should take with respect to MIPS. We believe that this is the most efficient method for dissemination of this information to all QPs, Partial QPs, and MIPS eligible clinicians.

We seek comment on our proposals to make the QP and Partial QP status notifications. We also seek comment on an alternative approach for Shared Savings Program ACOs in which we would separately notify each billing TIN participating in the ACO. We seek comment on other methods and media for the notification of QP and Partial QP status. We also seek comment on the content of such notifications so that they may be as clear and useful as possible.

6. Qualifying APM Participant Determination: Medicare Option

a. In General

Under the Medicare Option, we propose to calculate a Threshold Score for an Advanced APM Entity—or eligible clinician in the cases of an exception described in section II.F.5.b of this preamble—based on participation in an Advanced APM by analyzing claims for Medicare Part B covered professional services. Under the alternative calculation using patient counts in lieu of payments (patient count method), we propose to similarly calculate a Threshold Score for the Advanced APM Entity based on patient attribution as described below. Under either the payment amount or patient count method, only Medicare Part B covered professional services under the physician fee schedule will count toward the numerator and denominator of the Threshold Score calculation.

Section 1833(z)(2)(A), (B)(i) and (C)(i) of the Act describes the QP determination using the Medicare payment method as follows: A QP is an eligible clinician whose payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an Advanced APM Entity. Section 1833(z)(2)(D) of the Act describes the basis for the patient count method.

(1) Definitions

In section II.F.3 of this preamble, we propose two definitions that would apply specifically for the purposes of QP determination: Attributed beneficiary and attribution-eligible beneficiary. Each term describes a particular relationship between an Advanced APM Entity and the beneficiaries for whose cost and quality of care the participating eligible clinicians are held accountable. These terms are the foundation for how we propose to count services furnished through an Advanced APM Entity.

In section II.F.3 of this preamble, we propose that "attributed beneficiary" be defined as a beneficiary attributed to the Advanced APM Entity on the latest available list of attributed beneficiaries during the QP Performance Period based on each APM's respective attribution rules. There are some natural advantages to using this term for the purposes of QP determination because it is consistent with how many APMs—including the Shared Savings Program (assigned beneficiaries), Next Generation ACO Model (aligned beneficiaries*)*, and BPCI Model (attributed beneficiaries*)* identify the beneficiaries whose outcomes and costs are included in an APM Entity's assessment. We believe that using the same construct also coordinates the incentives under the Advanced APM with the incentives under MACRA by addressing the same beneficiary population.

In most episode payment models, such as the CJR Model, attribution is defined by the beneficiaries who trigger the defined episode of care under the model, often by presenting with a specific condition at the location of a participating APM Entity. In many attribution-based APMs, such as ACO initiatives or the Comprehensive Primary Care Initiative, CMS attributes beneficiaries to APM Entities through claims-based algorithms that identify the APM Entity with the plurality of evaluation and management visits for a beneficiary. In addition, most APMs do not allow beneficiaries to be attributed to more than one APM Entity. This means that the greater the APM Entity density in a market, the lower the attributed population for a given APM Entity will be as a percent of its total beneficiaries. We seek comment on the proposed methodology for defining the attributed beneficiary population, including comment on alternative methods for capturing the most meaningful cohort of attributed beneficiaries.

Under these plurality-based approaches, typically only 30–50 percent of an Advanced APM Entity's total population of beneficiaries for whom its eligible clinicians furnish services are actually attributed to the Advanced APM Entity for a performance period. These percentages reflect a combination of CMS' design decisions, beneficiaries' underlying care patterns, and the fact that beneficiaries in Medicare FFS retain freedom of choice to select clinicians. These percentages reflect conditions that are not entirely under the control of the APM Entity or its eligible clinicians. Thus, we recognize that because Advanced APMs have different attribution methodologies, using the specific Advanced APM attributed beneficiary as the definition may create a standard that advantages or disadvantages participation in certain Advanced APMs relative to others simply based on the specific attribution policies.

The unintended consequence would be that greater APM participation in a given market could make it impossible for many highly engaged Advanced APM Entities to reach a 50 percent or 75 percent QP Payment Amount Threshold. The result could be that an ACO functioning under arrangements with significant financial risk, (for example, in the Next Generation ACO Model or Track 3 of the Shared Savings Program), would still not meet the QP threshold, particularly in later years of the program under higher thresholds. We believe this would undercut our stated CMS goal of broadly increasing participation in advanced APMs, and we have attempted to compensate for these differences with how we propose to define the terms attributed beneficiary and attribution-eligible beneficiary for the purposes of making QP determinations.

Consistent with our proposed definition of attributed beneficiary, our proposed definition for an attribution-eligible beneficiary would allow us to be more consistent across Advanced APMs in how we consider the population of beneficiaries served by an Advanced APM Entity for the purposes of QP determination. To be attributed to an Advanced APM Entity in an Advanced APM, a beneficiary is first required to first meet certain eligibility criteria. Specifically, for purposes of QP determinations, we propose that an attribution-eligible beneficiary would be one who:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan.

(2) Does not have Medicare as a secondary payer.

(3) Is enrolled in both Medicare Parts A and B.

(4) Is at least 18 years of age.

(5) Is a United States resident.

(6) Has a minimum of one claim for evaluation and management services by an eligible clinician or group of eligible clinicians within an APM Entity for any period during the QP Performance Period.

An attribution-eligible beneficiary may or may not be an attributed beneficiary. Attributed beneficiaries are a subset of attribution-eligible beneficiaries. Much like the term "attributed beneficiary," the term attribution-eligible beneficiary is generally consistent with the attribution methodologies used in most current APMs—such as the Shared Savings Program and the Next Generation ACO Model—to identify the beneficiaries who could potentially be attributed to an APM Entity. Although the factors we are proposing for the definition of an attribution-eligible beneficiary in this context would only apply for the purposes of QP determinations, and would not change APM-specific methodologies, we believe that the factors in the proposed definition are representative of the methodologies most current APMs use to perform attribution. Therefore, we believe it would serve as a practical common set to apply in QP threshold calculations.

The purpose of using the attribution-eligible construct is to ensure that the denominator of QP determination calculations described in this section only includes payments for services furnished to patients who could potentially be attributed to an Advanced APM Entity under the Advanced APM, and thus could also appear in the numerator of the QP determination calculations. We believe that including amounts in the denominator that could not possibly be included in the numerator would be arbitrarily punitive toward certain Advanced APM Entities that furnish services to a substantial population of non-attribution-eligible beneficiaries.

We note that specialty-focused or disease-specific APMs may have attribution methodologies that are not based on evaluation and management services. Therefore, we anticipate needing targeted exceptions, especially related to the sixth factor of the definition of attribution-eligible beneficiary, for such APMs so that the attributed beneficiary population is truly a subset of the attribution-eligible population. Such exceptions would be made either through rulemaking or using available waiver authority and would be announced when the APM is announced.

For example, under the CEC Model, one criterion, among others, to be an aligned beneficiary requires that the beneficiary receive maintenance dialysis services. In the event that the CEC Model were determined to be an Advanced APM, we would consider attribution-eligible beneficiaries for the APM Entities participating in the CEC Model to be beneficiaries that meet the first five criteria outlined above and that have had at least one maintenance dialysis service billed through the Advanced APM Entity during the QP Performance Period. We would make this exception for the CEC Model to ensure that the denominator of QP determination calculations described in this section only includes payments for services furnished to patients who could potentially be attributed to an Advanced APM Entity under the Advanced APM.

Although the availability of such exceptions, as outlined above, would create multiple standards, we believe this slightly more complex approach is more appropriate and equitable because it is consistent with the design of APMs. An alternative approach could be to have a simple standard that includes in the denominator all beneficiaries who are furnished any Medicare Part B covered professional service by eligible clinicians participating the Advanced APM Entity.

We seek comment on the proposed general definition of attribution-eligible beneficiary. We further seek comment on our proposal to use of APM-specific standards as necessary to fulfill our expressed goals for specialty- or disease-focused APMs that may use alternative attribution methodologies.

(2) Attribution

We propose to use the attributed beneficiaries on Advanced APM attribution lists generated by each Advanced APM in making QP determinations. We also propose that the attributed beneficiary list would be taken from the Advanced APM's latest available list at the end of the QP Performance Period prior to making the QP determinations. For episode payment models, attributed beneficiaries would be those beneficiaries who trigger episodes of care under the terms of the APM.

We believe that this approach to attribution lists maintains consistency with the panel of beneficiaries for whom Advanced APM Entities are responsible under their respective Advanced APMs during the QP Performance Period. Therefore, we believe that such lists would be appropriate for use in QP determinations. Advanced APM Entities are already accustomed to providing care for the panel of beneficiaries represented by their APM Entity specific list. We believe that our proposal to link attribution for QP determination to Advanced APM attribution lists further strengthens the goals of the Advanced APMs in which these Advanced APM Entities participate. By using the same beneficiary population for QP determination purposes, Advanced APM Entities may continue focusing on the care they furnish to the same panel of attributed beneficiaries, instead of shifting focus and changing practice patterns to reach a QP threshold. As stated in our principles in section II.F.1 of this preamble, we intend for the QP determination process to seamlessly reward participation in the most advanced APMs, not to create a new set of performance standards distinct from the goals of APMs.

We seek comment on our proposal for determining which beneficiaries are considered attributed to an Advanced APM Entity for a QP Performance Period.

b. Payment Amount Method

This section describes our proposal for calculating a Threshold Score for the eligible clinician group in an Advanced APM Entity—or individual eligible clinician in the exception situations under section II.F. 6 of this preamble—using the payment amount method, which would then be compared to the relevant QP Payment Amount Threshold and Partial QP Payment Amount Threshold to determine if the eligible clinician meets the QP status for a payment year.

(1) Claims Methodology and Adjustments

For the payment amount method, section 1833(z)(2)(A), (B)(i) and (C)(i) of the Act requires that we use payments for Medicare Part B covered professional services to make QP determinations.

Covered professional services are defined under section 1848(k)(3)(A) of the Act as services for which payment is made under, or based on, the PFS. The payment amounts discussed in this proposal only include payments for Medicare Part B services under, or based on, the Physician Fee Schedule, even if an Advanced APM bases attribution and/or financial risk on payments other than or in addition to Medicare Part B payments.

We propose to use all available Medicare Part B claims information generated during the QP Performance Period. Additionally, we propose that CMS will treat claims run-out, claims adjustments, supplemental service payments, and alternative payment methods in the same manner for purposes of calculating both the Threshold Score and for determining the APM Incentive Payment amount. We further detail our proposals to account for claims run-out, claims adjustments, non-claims-based payments, and alternative payment methods in section II.F.8 of this preamble.

We believe it is appropriate to maintain consistency across the QP determination and the incentive payment calculation in order to support internal CMS operational consistencies. It also ensures that any unique payment mechanisms within an Advanced APM do not affect the opportunity for an eligible clinician to reach the QP threshold.

We seek comment on whether the claims methodology we use under the Medicare payment method should align with the proposed claims methodology for purposes of calculating the estimated aggregate payment amount for the APM Incentive Payment.

(2) Threshold Score Calculation

In general, our proposed method for deriving a Threshold Score for an Advanced APM Entity is to divide the value described under paragraph (a) below by the value described under paragraph (b) below. This calculation would result in a percent value that CMS would compare to the QP Payment Amount Threshold and the Partial QP Payment Amount Threshold to determine the QP status for all eligible clinicians in the Advanced APM Entity for the payment year.

(a) Numerator

We propose that the numerator for this calculation would be the aggregate of all payments for Medicare Part B covered professional services furnished by the eligible clinicians in the Advanced APM Entity to attributed beneficiaries during the QP Performance Period.

We believe that this method is the most logical reading of the statute and is reflective of the population of beneficiaries for whom an Advanced APM Entity is responsible for cost and quality. Therefore, we believe that counting payments for covered professional services furnished to attributed beneficiaries is the most suitable metric for payments that are attributable to services furnished "through" an Advanced APM Entity. In episode payment models, because a beneficiary is considered attributed during the course of an episode, the payments included in the numerator for this calculation are those for Medicare Part B covered professional services furnished to an attributed beneficiary by eligible clinicians in the Advanced APM Entity during the course of an episode.

One program integrity concern is that an Advanced APM Entity might meet the higher QP Payment Amount Threshold in later years by providing substantially disproportionate amounts of care for attributed beneficiaries relative to all others. However, because of the financial risk an Advanced APM Entity bears, which is usually based on expenditures, we believe that the relatively large potential loss under the Advanced APM would outweigh the advantage of any overutilization geared toward abusing Threshold Score calculations.

We seek comment on any alternative numerators we could use for purposes of the Medicare payment method that meaningfully meet statutory requirements, are understandable, and operationally feasible.

(b) Denominator

We propose that the denominator in the Medicare payment method would be the aggregate of all payments for Medicare Part B covered professional services furnished by the eligible clinicians in the Advanced APM Entity to attribution-eligible beneficiaries during the QP Performance Period. We propose that when the QP determination is made at the eligible clinician level as described in section II.F.5 of this preamble, the denominator will be the total of all payments for Medicare Part B covered professional services furnished to attribution-eligible beneficiaries by the eligible clinician. In episode payment models, the payments included in the denominator for this calculation are those for Medicare Part B covered professional services furnished to any attribution-eligible beneficiary by eligible clinicians in the Advanced APM Entity. This includes all such services to all attribution-eligible beneficiaries whether or not such services occur during the course of an episode under the Advanced APM.

We believe that this denominator represents a meaningful alignment with the way in which current APMs perform attribution. Including payment for services furnished only to attribution-eligible beneficiaries standardizes the denominator to ensure fairness across types of eligible clinicians and geographic regions. By using the attribution-eligible population, the denominator will not penalize entities for furnishing services to beneficiaries who could not possibly be in the numerator through attribution under an Advanced APM. For example, an ACO's eligible clinicians may furnish services to a large population of beneficiaries with Medicare as a secondary payer. Those beneficiaries may not be eligible for attribution to the ACO, and could never be included in the numerator. Therefore, we believe that this methodology focuses on factors for which Advanced APM Entities have some control rather than those for which they may have no control or that disadvantage certain organizational structures or types of APMs. We seek comment on alternative methods that are consistent with the statutory language.

c. Patient Count Method

Similar to the Medicare payment method, this section describes our proposal for calculating a Threshold Score for the eligible clinicians participating in an Advanced APM Entity—or eligible clinician in situations under section II.F.6 of this preamble—using the Medicare patient count method, which would then be compared against the relevant QP Patient Count Threshold and Partial QP Patient Count Threshold to determine the QP status of an eligible clinician for the year. Given our authority under section 1833(z)(2)(D) of the Act to use patient counts in lieu of payments "as the Secretary determines appropriate," we are interpreting the patient count method to offer a more flexible alternative to the payment method. As previously mentioned, the purpose of the proposed design of the Medicare patient count method is to make QP status determinations accessible to entities and individuals who are clearly and significantly engaged in delivering value-based care through participation in Advanced APMs.

(1) Unique Beneficiaries

We propose that when counting the number of beneficiaries under this method, CMS may count a given beneficiary in the numerator and denominator for multiple different Advanced APM Entities. For example, during a year, a beneficiary may be attributed to an ACO, Advanced APM Entity 1, be treated for an episode of care for a particular condition in a hospital participating in an episode payment model as Advanced APM Entity 2, and receive a few services from eligible clinicians in Advanced APM Entity 3. The beneficiary could be included in the numerator and denominator for Advanced APM Entity 1 and Advanced APM Entity 2 and in the denominator for Advanced APM Entity 3. However, the beneficiary could not be counted more than once under the proposed exception for determining QP status for individual eligible clinicians that do not reach QP status under a single Advanced APM; for this exception, each attributed beneficiary would only be counted once in the numerator, and the denominator would consist of all unique attribution-eligible beneficiaries for whom the eligible clinician received payment for covered Medicare professional services for the QP Performance Period.

This is a distinct issue from the question of whether CMS pays shared savings to APM Entities more than once for a given beneficiary. Such payment overlap issues are handled separately through CMS' operational rules governing APM initiative overlaps that address double payments, and are not affected by decisions regarding QP Threshold Score calculations discussed in this regulation.

We propose that CMS will not count any beneficiary more than once for any single Advanced APM Entity. In other words, for each Advanced APM Entity, CMS will count each unique beneficiary no more than one time in the numerator and one time in the denominator.

We believe that counting beneficiaries this way retains integrity of the Threshold Scores by preventing double counting of beneficiaries within an Advanced APM Entity while recognizing the reality that beneficiaries often have relationships with eligible clinicians in different organizations. We seek comment on our proposal for counting beneficiaries.

(2) Claims Methodology and Adjustments

To be consistent with the Medicare payment method, we propose that beneficiary counts would be based on any beneficiary for whom the eligible clinicians within an Advanced APM Entity receive payments for Part B covered professional services, even if an Advanced APM bases its attribution and/or financial risk on both Parts A and B. We propose that for this Threshold Score calculation, we would use any and all available Part B claims information generated during the QP Performance Period.

(3) Threshold Score Calculation

We propose that the Threshold Score would be calculated under the Medicare patient count method as a percent, by dividing the value described under paragraph (a) below by the value described under paragraph (b) below. We include the formula and examples in the summary equation below.

(a) Numerator

We propose that the numerator would be the number of unique attributed beneficiaries to whom eligible clinicians in the Advanced APM Entity furnish Medicare Part B covered professional services during the QP Performance Period. For episode payment models, this would include the number of attributed beneficiaries furnished Medicare Part B covered professional services by eligible clinicians in the Advanced APM Entity during the course of an episode under the Advanced APM.

(b) Denominator

We propose that the denominator would be the number of attribution-eligible beneficiaries to whom eligible clinicians in the Advanced APM Entity furnish covered professional services during the QP Performance Period. For episode payment models, this would include the number of attribution-eligible beneficiaries furnished Medicare Part B covered professional services by eligible clinicians in the Advanced APM Entity group at any point during the QP Performance Period, irrespective of whether such services occur during the course of an episode.

(c) Summary Equation

The proposed Medicare patient score method Threshold Score calculation can be summarized with the following equations.

Threshold Score = A/B

For episode payment models, the equation is:

Threshold Score = A/B

Where:

A = The numerator value under paragraph (a) above.
B = The denominator value under paragraph (b) above.

TABLE 37: Example of Threshold Score Calculation

	(A) # of Attributed Beneficiaries	(B) # of Attribution-Advanced Beneficiaries	Threshold Score (A/B)
Advanced APM Entity 1	500	1,000	50%
Advanced APM Entity 2	300	1,200	25%

In general, we believe that through consistency with the payment amount method this approach balances our interests of relative simplicity and having a meaningful standard that recognizes the common aspects of attribution and accountability under Advanced APMs. Similar to the payment amount method, the patient count method represents a proportion of the patients for whom an Advanced APM Entity is accountable under the Advanced APM with respect to all patients who could potentially be attributed to the Advanced APM Entity under the Advanced APM. We believe that it important from any equity perspective to not include patients in the denominator if there is no possibility—based on Advanced APM attribution methodologies—that such individuals could be included in the numerator. We note that although we believe this method to be a fair assessment of the degree of participation in an Advanced APM, our preliminary analyses indicate that many Advanced APM Entities would still miss high thresholds set for later years of the Quality Payment Program.

We seek comment on alternative approaches to the patient count method that would achieve our goal of a simple and meaningful Threshold Score calculation.

(4) Participation in Multiple Advanced APMs

We propose that if the same Advanced APM Entity participates in multiple Advanced APMs and if at least one of those Advanced APMs is an episode payment model, that we would add the number of unique beneficiaries in the numerator of the episode payment model Advanced APM Entity to the numerator(s) for non-episode payment models in which the Advanced APM Entity participates. For example, if an Advanced APM Entity is an ACO in Track 3 of the Shared Savings Program and also in the OCM, (both of which are hypothetically considered to be Advanced APMs for purposes of this example), we would add the entity's unique attributed beneficiaries in OCM to the numerator for its Shared Savings Program Track 3 Threshold Score calculation. We propose that for purposes of this proposal, Advanced APM Entities would be considered the same if CMS determines, that the eligible clinician participant lists are the same or substantially similar, or if the Advanced APM Entity participating in one Advanced APM is the same as, or is a subset of, the other.

The purpose of this proposal is to allow the logical combination of activities under multiple Advanced APMs where appropriate. We believe that the purpose of the incentives for Advanced APM participation is to capture the degree of Advanced APM participation generally, not simply the degree of participation within a single Advanced APM. Where relevant and operationally feasible, we want this program to encourage participation in multiple Advanced APMs. The counterfactual where we would not account for a single Advanced APM Entity's participation in multiple Advanced APMs could be seen as punitive. For instance, an Advanced APM Entity could serve the vast majority of its beneficiaries through several Advanced APMs, but unless that participation is aggregated, the entity could end up with several lower Threshold Scores that are below the QP Patient Count Threshold and not indicative of its broader participation.

We understand the difficulty associated with determining whether two Advanced APM Entities are in fact the same organization. It is highly unlikely that their participant lists will be exactly the same. Therefore, we seek comment on how best to make a determination of substantial similarity, which includes, for example, matching organizational information, aligning TINs, and comparing participant lists. We also seek comment on percentages of participant list or TIN similarity that would be sufficient for APM Entities to be considered under this policy.

d. Use of Methods

CMS may apply one or both of two different methods—using payment amounts or patient counts—to arrive at an eligible clinician's Threshold Score. CMS will compare the Threshold Score against the relevant QP Threshold or Partial QP Threshold to determine an eligible clinician's QP status for the year.

We propose that CMS would calculate Threshold Scores for eligible clinicians in an Advanced APM Entity under both the payment amount and patient count methods for each QP Performance Period. We also propose that CMS would assign QP status using the more advantageous of the Advanced APM Entity's two scores.

We believe that both the payment amount and patient count methods should be considered in order to produce Threshold Scores. As the two calculations differ there may be cases in which Threshold Scores vary enough that different QP determinations could result depending on which is used. In such an event, we do not believe that prioritizing the Threshold Score using one calculation over the other would yield an appropriate, non-arbitrary result. By using the greater of the Threshold Scores achieved, we hope to promote simplicity in QP determinations and to maximize the number of eligible clinicians that attain QP status each year. We seek comment on the use of the payment and patient count methods for the Medicare Option.

e. Services Furnished Through CAHs, FQHCs, and RHCs

(1) Critical Access Hospitals (CAHs)

We propose that professional services billed by CAHs under section 1834(g)(2)(B) of the Act (Method II CAH professional services) would count towards the QP determination threshold calculations for both the Medicare payment and patient count methods in both the numerator and the denominator, as applicable. We believe these services would constitute "covered professional services" under section 1848(k)(3) of the Act because they are furnished by an eligible clinician and payment is based on the Medicare PFS. This policy is consistent with our treatment of payments for Method II CAH professional services for purposes of the EHR Incentive Program and PQRS adjustments under sections 1848(a)(7) and (8) of the Act, respectively. Under section 1848(a)(7) and (8) of the Act, the PQRS and EHR Incentive Program adjustments are applied to payments for covered professional services furnished by an eligible clinician in a Method II CAH.

CAHs were established under the Balanced Budget Act (BBA) of 1997 as a separate provider type with a distinct set of Medicare Conditions of Participation and their own payment methodology. CAHs are not subject to the Medicare Inpatient Prospective Payment System (IPPS) or the Medicare Outpatient Prospective Payment System (OPPS). Instead, CAHs are generally paid based on 101 percent of reasonable costs for inpatient services and are paid for outpatient services under one of two methods: The Standard Payment method outlined in section 1834(g)(1) of the Act (Method I), or the Optional Payment Method outlined in section 1834(g)(2) of the Act (Method II). A CAH is paid under Method I unless it elects to be paid under Method II.

Under Method I, for cost reporting periods beginning on or after January 1, 2004, payments to CAHs are made for outpatient CAH facility services at 101 percent of reasonable costs. Physicians and practitioners receive payment for professional services under the Medicare PFS. A CAH may elect Method II billing, under which the CAH bills Medicare for both facility services and professional services furnished to its outpatients by a physician or practitioner who has reassigned his or her billing rights to the CAH. Even if a CAH makes this election, each physician or practitioner who furnishes professional services to CAH outpatients can choose to either: (1) Reassign his or her billing rights to the CAH, agree to be included under the Method II billing, attest in writing that he or she will not bill Medicare for professional services furnished in the CAH outpatient department, and receive payment from the CAH for the professional services; or (2) elect to file claims for his or her professional services with Medicare for standard payment under the Medicare PFS.

As of January 1, 2004, payment for a physician's professional services provided at a CAH billing under Method II is 115 percent of the allowable amount, after applicable deductions, under the Medicare PFS. For a non-physician practitioner's professional services, the payment amount is 115 percent of the amount that otherwise would be paid for the practitioner's professional services, after applicable deductions, under the Medicare PFS.

(2) Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

RHCs and FQHCs are facilities that furnish services that are typically furnished in an outpatient clinic setting. They are located in areas that have been designated as HPSAs, and meet other requirements.

Under section 1833(a)(3) of the Act, RHCs are paid an all-inclusive rate (AIR) based on reasonable costs, subject under section 1833(f) of the Act to a maximum payment per visit that is established by Congress and updated annually based on the percentage change in the Medicare Economic Index (MEI) and subject to annual reconciliation. The per-visit limit does not apply to RHCs determined to be an integral and subordinate part of a hospital with fewer than 50 beds. Laboratory tests (excluding venipuncture) and technical components of RHC services are paid separately. The RHC payment limit per visit for CY 2016 is $81.32, effective January 1, 2016, through December 31, 2016.

The FQHC Medicare benefit was added when section 1861(aa) of the Act was amended by section 4161 of the Omnibus Budget Reconciliation Act of 1990. FQHCs are paid according to the FQHC PPS set out under section 1834(o) of the Act, in which Medicare pays a national encounter based rate per beneficiary per day, with some adjustments based on where and by whom the services are furnished. The unadjusted 2016 PPS rate is $160.60.

We propose that professional services furnished at RHCs and FQHCs that participate in ACOs, and are reimbursed under the RHC AIR or FQHC PPS (respectively), be counted towards the QP determination calculations under the patient count method but not under the payment amount method.

In certain Medicare ACO APMs, RHC and FQHC services can be counted for purposes of attributing beneficiaries to an ACO. Therefore, we propose to include beneficiaries attributed to an Advanced APM Entity in full or in part because of services furnished by RHCs or FQHCs in the patient counts used for QP determination calculations.

As previously stated, section 1833(z)(2)(D) of the Act permits us to use patient counts in lieu of payments when determining whether an eligible clinician is a QP "as the Secretary determines appropriate." Our proposal to include the professional services furnished by eligible clinicians at RHCs and FQHCs in the QP threshold calculations for the patient count method is essential to assure consistency with this program and existing APM attribution methodologies. An Advanced APM Entity is responsible for the cost and quality of care for all beneficiaries attributed to an APM Entity, including all professional services furnished to such beneficiaries, regardless of whether or not attribution was based on services furnished by an eligible clinician or by an RHC or FQHC. We believe such beneficiaries are clearly served through the Advanced APM Entity, and it would be potentially confusing to eligible clinicians and Advanced APM Entities to track this distinction strictly for purposes of QP determination. We also believe that it would be unduly burdensome and impractical for CMS to develop and maintain a separate list of beneficiaries aligned to each Advanced APM Entity from the full list of beneficiaries for whom an Advanced APM Entity is responsible under an Advanced APM.

Because professional services furnished by eligible clinicians at RHCs and FQHCs are not reimbursed under, or based on, the Medicare PFS, professional services furnished in these settings do not constitute "covered professional services" under section 1848(k)(3)(A) of the Act. In the Medicare Payment Amount Method, where payments for specified covered professional services are summed, only payments for covered professional services can be included.

We believe that our proposal will continue to encourage the development of APMs that span rural and/or underserved areas. We seek comment on this proposal.

7. Combination All-Payer and Medicare Payment Threshold Option

a. Overview

Beginning in 2021, in addition to the Medicare Option, eligible clinicians may also become QPs through the All-Payer Combination Option, described under section 1833(z)(2)(B)(ii) and (C)(ii) of the Act as the Combination All-Payer and Medicare Payment Threshold Option. Thus, there will be two avenues for eligible clinicians to become QPs—the Medicare Option and the All-Payer Combination Option—and an eligible clinician need only meet the QP threshold under one of them to be a QP for the payment year. The All-Payer Combination Option provides an incentive for eligible clinicians to participate in arrangements with non-Medicare payers that have payment designs similar to those in Advanced APMs. The All-Payer Combination Option uses both the methods described in the Medicare Option and methods that calculate payments for all services from all payers, with certain exceptions, that are attributable to participation in both Advanced APMs and Other Payer Advanced APMs.

Although the statutory QP threshold for an eligible clinician to be a QP (the QP Payment Amount Threshold) under the Medicare Option increases from 25 percent in 2019 and 2020 under section 1833(z)(2)(A) of the Act, to 50 percent in 2021 and 2022 under section 1833(z)(2)(B)(i) of the Act, to 75 percent beginning in 2023 under section 1833(z)(2)(C)(i) of the Act, the All-Payer Combination Option allows eligible clinicians with lower levels of participation in Advanced APMs to become QPs through sufficient participation in Other Payer Advanced APMs with payers such as State Medicaid programs and commercial payers, including Medicare Advantage plans. Similar to Medicare payment amount and patient count methods the statute also allows, under section 1833(z)(2)(D) of the Act, the QP determination to be based on payment amount or on counts of patients in lieu of payments using the same or similar percentage criteria. These QP thresholds are presented in Tables 38 and 39, and the process is shown in Figures J and K. The process shown in H and I will be similar for the patient count threshold, although only the process for the payment amount threshold is displayed. CMS may reassess the QP Patient Count Thresholds in future years based on the experience gained from eligible clinician Threshold Scores during the first years of operations. In summary, eligible clinicians may become QPs if the following steps occur as described below in the associated sections: (1) The eligible clinician submits to CMS sufficient information on all relevant payment arrangements with other payers; (2) CMS determines that an Other Payer APM is an Other Payer Advanced APM; (3) the eligible clinician meets the relevant QP thresholds by having sufficient payments or patients attributed to a combination of participation in Advanced APMs and Other Payer Advanced APMs.

TABLE 38: QP Payment Amount Thresholds – All-Payer Combination Option

All-Payer Combination Option – Payment Amount Method										
Payment Year	**2019**	**2020**	**2021**		**2022**		**2023**		**2024 and later**	
QP Payment Amount Threshold	N/A	N/A	50%	25%	50%	25%	75%	25%	75%	25%
Partial QP Payment Amount Threshold	N/A	N/A	40%	20%	40%	20%	50%	20%	50%	20%
			Total	Medicare	Total	Medicare	Total	Medicare	Total	Medicare

TABLE 39: QP Patient Count Thresholds – All-Payer Combination Option

All-Payer Combination Option – Patient Count Method										
Payment Year	**2019**	**2020**	**2021**		**2022**		**2023**		**2024 and later**	
QP Patient Count Threshold	N/A	N/A	35%	20%	35%	20%	50%	35%	50%	35%
Partial QP Patient Count Threshold	N/A	N/A	25%	10%	25%	10%	35%	25%	35%	25%
			Total	Medicare	Total	Medicare	Total	Medicare	Total	Medicare

FIGURE J: QP Determination Tree, Payment Years 2021-2022

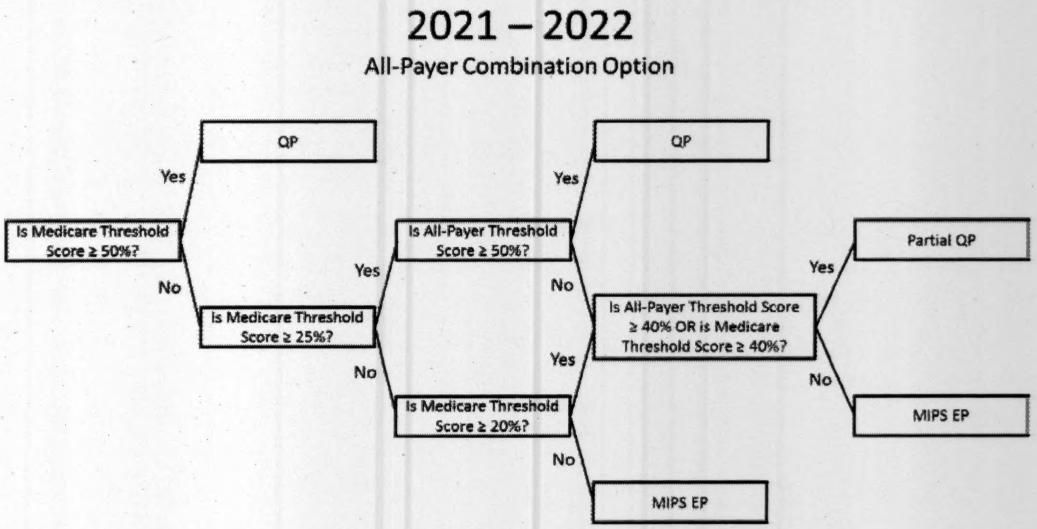
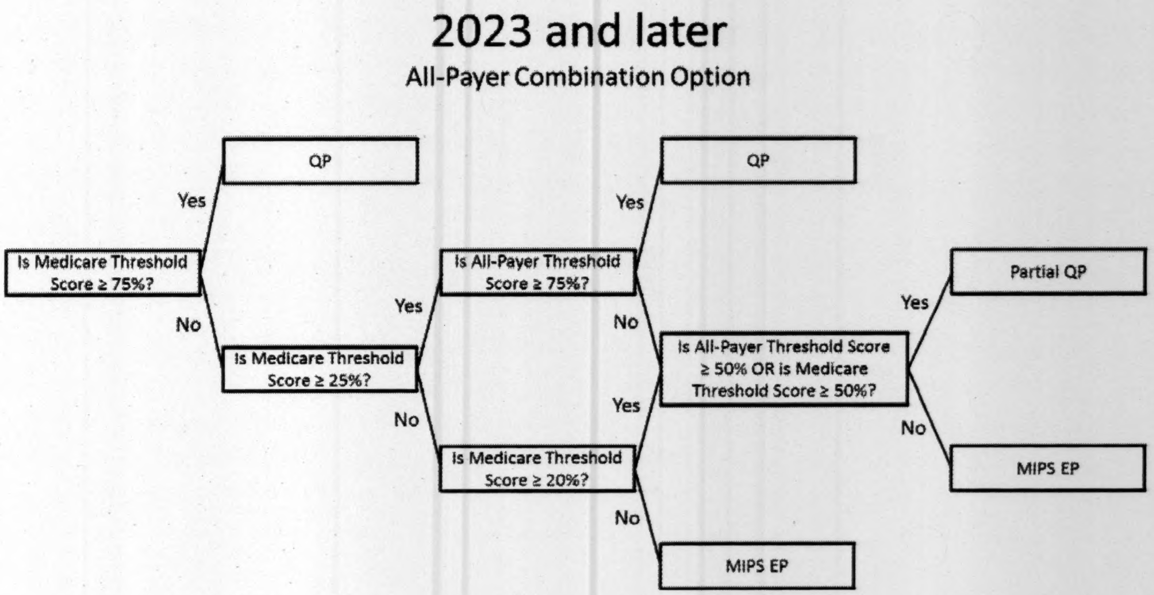

2021 – 2022
All-Payer Combination Option
Is Medicare Threshold Score ≥ 50%?
Yes
QP
No
Is Medicare Threshold Score ≥ 25%?
Yes
Is All-Payer Threshold Score ≥ 50%?
Yes
QP
No
Is All-Payer Threshold Score ≥ 40% OR is Medicare Threshold Score ≥ 40%?
Yes
Partial QP
No
MIPS EP
No
Is Medicare Threshold Score ≥ 20%?
Yes
No
MIPS EP

FIGURE K: QP Determination Tree, Payment Years 2023 and Later


2023 and later
All-Payer Combination Option
Is Medicare Threshold Score ≥ 75%?
Yes
QP
No
Is Medicare Threshold Score ≥ 25%?
Yes
Is All-Payer Threshold Score ≥ 75%?
Yes
QP
No
Is All-Payer Threshold Score ≥ 50% OR is Medicare Threshold Score ≥ 50%?
Yes
Partial QP
No
MIPS EP
No
Is Medicare Threshold Score ≥ 20%?
Yes
No
MIPS EP

Sections 1833(z)(2)(B)(ii) and (C)(ii) of the Act describe the payment amount method for making the QP determination under the All-Payer Combination Option. For purposes of making a QP determination under this option, a QP is an eligible clinician for whom we determine with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year) that, at least the specified percent of the sum of combined Medicare payments and all other payments regardless of payer are through Advanced APMs and Other Payer Advanced APMs that meet the criteria set forth in this section.

b. Other Payer Advanced APM Criteria

(1) In General

A payment arrangement with a non-Medicare payer (Other Payer APM) can become an Other Payer Advanced APM if the arrangement meets three criteria:

- Certified Electronic Health Record technology (CEHRT) is used;
- Quality measures comparable to measures under the MIPS quality performance category apply; and
- The APM Entity either: (1) Bears more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures; or (2) for beneficiaries under title XIX, is a medical home in a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act.

Other Payer APMs include payment arrangements under any payer other than traditional Medicare. Medicare Advantage and other Medicare-funded private plans are categorized as a payer other than traditional Medicare for these purposes. In this section, we explain how the three criteria are applied to determine whether arrangements are Other Payer Advanced APMs.

(2) Medicaid APMs

We propose to define a Medicaid APM as a payment arrangement under title XIX that meets the criteria to be an Other Payer Advanced APM as proposed in this section. States can choose from different authorities in title XIX when implementing new payment models. We believe this proposal would provide some flexibility for States but align the core requirements for Medicaid APMs with the broader Advanced APM and Other Payer Advanced APM criteria. Otherwise, we intend to generally defer to states in their design of payment arrangements.

(3) Medicaid Medical Home Models

We propose that a Medicaid Medical Home Model is a Medical Home Model that is operated under a State title XIX program instead of under section 1115A of the Act. Section 1833(z) of the Act mentions medical homes and what we have termed Medicaid Medical Homes (those with respect to beneficiaries under title XIX) several times, but does not define the terms. In addition, Medicaid Medical Home is not defined in title XIX or in Medicaid laws or regulations. Therefore, we need to define the terms because of their importance in the Quality Payment Program.

We propose that a Medicaid Medical Home Model must have the following elements at a minimum:

- Model participants include primary care practices or multispecialty practices that include primary care physician and practitioners and offer primary care services, and
- Empanelment of each patient to a primary clinician.

In addition to these elements, we propose that a Medicaid Medical Home Model must have at least four of the following elements:

- Planned chronic and preventive care.
- Patient access and continuity.
- Risk-stratified care management.
- Coordination of care across the medical neighborhood.
- Patient and caregiver engagement.
- Shared decision-making.
- Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings, population-based payments).

This definition of Medicaid Medical Home Model applies only for the purposes of the Quality Payment Program, and could be defined differently for other purposes. To define these terms, we reviewed existing and past Medical Home Models CMS developed under section 1115A of the Act, including the Comprehensive Primary Care Initiative (CPC). In addition, we reviewed a variety of other sources including several from the National Committee for Quality Assurance, the Joint Principles of the Patient-Centered Medical Home (a joint statement by the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, and the American Osteopathic Association), and the Agency for Healthcare Research and Quality. Our proposed definition of Medicaid Medical Home Model uses common elements from these sources. We believe that using a common set of elements ensures general comparability between Medical Home Models and Medicaid Medical Home Models while maintaining flexibility for the States under title XIX. In response to the MIPS and APMs RFI, some commenters suggested that we should require a specific method or accreditation process for recognizing Medicaid Medical Home Models, while others asked us not to use such an approach. We will not mandate a specific method or accreditation process. We believe that such a policy would provide limited additional benefit while unnecessarily restricting state innovation. However, we believe it likely that accredited models, such as those certified by the National Committee on Quality Assurance may also meet these proposed criteria. Medicaid Medical Home Models can be Other Payer Advanced APMs if they meet the criteria set forth in this section.

We seek comment on the definitions of Medicaid APMs and Medicaid Medical Homes Models.

(4) Use of Certified Electronic Health Record Technology

To be an Other Payer Advanced APM, as described under section 1833(z)(2)(B)(iii)(II)(bb) and (z)(2)(C)(iii)(II)(bb) of the Act, payments must be made under arrangements in which certified EHR technology is used. This is slightly different than the requirement for Advanced APMs that "requires participants in such model to use certified EHR technology (as defined in section 1848(o)(4) of the Act)," as specified in section 1833(z)(3)(D)(i)(I) of the Act. Although the statutory requirements are phrased slightly differently, we believe that there is value in keeping the two standards—for Advanced APMs and Other Payer Advanced APMs—as similar as possible.

We propose that Other Payer APMs would meet this Other Payer Advanced APM criterion under sections 1833(z)(2)(B)(iii)(II)(bb) and (z)(2)(C)(iii)(II)(bb) of the Act by requiring participants to use CEHRT as defined for MIPS and APMs under § 414.1305. This approach is consistent with the approach for Advanced APMs as described in section II.F.4.b.(1) of this preamble. In the 2015 EHR Incentive Programs final rule (80 FR 62872 through 62873), we established the definition of CEHRT for EHR technology that must be used by eligible clinicians to meet the meaningful use objectives and measures in specific years. In this proposed rule, we are proposing to adopt the specifications from within the current definition of CEHRT in our regulation at § 414.1305 for eligible clinicians participating in MIPS or in APMs. This definition is identical to the definition for use by eligible hospitals and CAHs and Medicaid eligible clinicians in the EHR Incentive Programs.

In accordance with section 1833(z)(2)(C)(iii)(II) of the Act, we propose that an Other Payer Advanced APM must require at least 75 percent of eligible clinicians in each participating APM Entity (or each hospital if hospitals are the APM participants) to use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals.

We seek comment on the proposed definition of CEHRT for Advanced APMs and Other Payer Advanced APMs and whether they should be the same for both. We seek comment on the proposed method for Other Payer APMs to meet the CEHRT use criterion.

(5) Application of Quality Measures Comparable to Those Under the MIPS Quality Performance Category

Another of the criteria to be considered an Other Payer Advanced APM, as described in sections 1833(z)(2)(B)(ii)(II)(aa) and (C)(iii)(II)(aa) of the Act, are quality measures comparable to those under MIPS quality performance category apply under the Other Payer APM. Under the MACRA and in this proposal, not all quality measures in an APM are required to be "comparable" and not all payments under the APM must be based on comparable measures. This approach is similar to the requirement for Advanced APMs as described in section II.F.4.b.(2) of this preamble. Under this proposal, Other Payer APMs retain sufficient freedom to innovate in paying for services and measuring quality. For instance, an Other Payer APM may have incentive payments related to quality, total cost of care, participation in learning activities, and adoption of health IT. The existence of all of the payments associated with non-quality aspects does not preclude the Other Payer APM from meeting this Other Payer Advanced APM criterion. In other words, this criterion only sets standards for payments tied to quality measurement, not other methods of payment. Conversely, an Other Payer APM may test new quality measures that do not fall into the MIPS-comparable standard. So long as the Other Payer APM meets the requirements set forth in this criterion, there is no additional prescription for how the Other Payer APM tests additional measures that may or may not meet the standards under this criterion. Therefore, we propose that the quality measures on which the Other Payer Advanced APM bases payment must include at least one of the following types of measures provided that they have an evidence-based focus and are reliable and valid as described in section II.F.4.b.(2) of this preamble:

(1) Any of the quality measures included on the proposed annual list of MIPS quality measures;

(2) Quality measures that are endorsed by a consensus-based entity;

(3) Quality measures developed under section 1848(s) of the Act;

(4) Quality measures submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(5) Any other quality measures that CMS determines to have an evidence-based focus and are reliable and valid.

We want to encourage the use of outcome measures for quality performance assessment in Other Payer APMs. As we did for APMs in section II.F.4.b.(2) of this preamble, we propose that in addition to the general comparable quality measure requirement proposed in this section, an Other Payer Advanced APM must include at least one outcome measure if an appropriate measure (that is, the measure addresses the specific patient population and is specified for the APM participant setting) is available on the MIPS list of measures for that specific QP Performance Period.

We believe that this framework will provide other payers the flexibility needed to ensure that their quality performance metrics meet their unique goals. We seek comment on this proposed criterion.

(6) Financial Risk for Monetary Losses

As described in sections 1833(z)(2)(B)(iii)(II)(cc) and (C)(iii)(II)(cc) of the Act, the third criterion that an Other Payer APM must meet to be an Other Payer Advanced APM is that under the arrangement, the APM Entity must either bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures or the Other Payer APM be a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act, as described in paragraph (d) below.

The financial risk standard under this criterion is similar to that proposed for the Advanced APM criterion. For purposes of determining whether the Other Payer APM is an Other Payer Advanced APM, this proposal does not impose any additional performance criteria, such as actual achievement of savings, on APM Entities in other payer arrangements. As with all the proposed Advanced APM criteria, this requirement pertains to the payment arrangement structure, not of the performance of the participants within the payment arrangement.

This section is broken into two main parts: (1) What it means for an Advanced APM Entity to bear financial risk if actual aggregate expenditures exceed expected aggregate expenditures under an Other Payer Advanced APM; and (2) what amounts of risk are considered to be more than nominal.

We prioritized keeping the standards consistent across different types of APMs, including Advanced APMs as described in section II.F.4.b.(3) of this preamble.

(a) Bearing Financial Risk for Monetary Losses

We propose a generally applicable standard for Other Payer Advanced APMs and a slightly different standard for Medicaid Medical Home Models. We want to be consistent with and comparable to the Advanced APM financial risk standard within the limits of the statutory text.

(i) Generally Applicable Other Payer Advanced APM Standard

We propose that the generally applicable financial risk standard for Other Payer Advanced APMs would be that a payment arrangement must, if APM Entity actual aggregate expenditures exceed expected aggregate expenditures during a specified performance period:

- Withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians; or
- Require direct payments by the APM Entity to the payer.

We believe this financial risk criterion best distinguishes most Other Payer APMs from those that are focused on challenging physicians and practitioners to assume risk and provide high value care. We expect that an increasing proportion Other Payer APMs will meet that bar over time. This proposal is based on the statutory requirement that the APM Entity bear risk if aggregate actual expenditures exceed aggregate expected expenditures under the model, and is consistent with our proposal for the corresponding criterion proposed for Advanced APMs. Through the MIPS and APM RFI, many stakeholders commented that business risk should be sufficient to meet this Advanced APM criterion. We do not intend for our proposal to minimize the substantial time and financial commitments that APM Entities invest to become successful APM participants. We note that there is also difficulty in creating an objective and enforceable standard for determining whether an entity's business risk exceeds a nominal amount, and that the statutory framework for the APM Incentive Payment recognizes that not all alternative payment arrangements will meet the criteria to be considered for purposes of the QP determination. We seek comments regarding the proposed standard and whether there are other types of arrangements that should be incorporated into the standard.

(ii) Medicaid Medical Home Model Financial Risk Standard

We propose that for a Medicaid Medical Home Model to be an Other Payer Advanced APM if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures, the APM must:

- Withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- Require direct payment by the APM Entity to the payer; or
- Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

For instance, a Medicaid Medical Home Model would meet our proposed financial risk criterion if it conditions the payment of some or all of a regular care management fee to medical home APM Entities upon expenditure performance in relation to a benchmark. Because the arrangement would require no direct payment as a consequence for failure to meet expenditure standards, such a medical home would not necessarily be worse off than it had been prior to the decreased payment. However, it would be worse off in the future than it otherwise would have been had it met expenditure standards. Similarly, a Medicaid Medical Home Model that offers expenditure and quality performance payments in addition to payment withholds that can be earned back for meeting minimum requirements would also meet this criterion. Consistent with the treatment of Medical Home Models under the statute, this proposal acknowledges the unique challenges of medical homes in bearing risk for losses while maintaining a more rigorous standard than mere business risk.

We believe that because Medicaid Medical Home Models are unique types of Medicaid APMs and because they are identified and treated differently by the statute under the Quality Payment Program, it is appropriate to establish a unique standard for bearing financial risk that reflects these differences and remains consistent with the statutory scheme, which is to provide incentives for participation by eligible clinicians in advanced APMs.

Similar to Medical Home Model standards for Advanced APMs in II.F.4.b.(3), we believe that it would be appropriate to impose size and composition limits for Medicaid Medical Home Models to ensure that the focus is on organizations with a limited capacity for bearing the same magnitude of financial risk as larger APM Entities do. We propose that this limit would only apply to APM Entities that participate in Medicaid Medical Home Models and that have 50 or fewer eligible clinicians in the organization through which the APM Entity is owned and operated. Thus, in a Medicaid Medical Home Model that is an Other-Payer Advanced APM, only those APM Entities that are part of a parent organization with 50 or fewer eligible clinicians would be Advanced APM Entities. We believe it is appropriate to use eligible clinicians, rather than physicians, when setting this threshold as the number of eligible clinicians both reflects organizational resources and capacity and also may differ substantially across organizations with the same number of physicians.

We also believe that this size threshold of 50 eligible clinicians is appropriate as organizations of that size have demonstrated the capacity and interest in taking on risk, and organizations may also join together to take on risk collectively, for example, in an ACO. In the event that a Medicaid Medical Home Model happens to have criteria that meet the Advanced APM financial risk criterion that is generally applicable to all Other Payer APMs, this organizational size limitation would be moot.

There are several unique aspects of Medicaid Medical Home Models, which statute specifically singles out for unique treatment, and their participating APM Entities (medical homes) that support the need for a separate standard to assess financial risk if actual expenditures exceed expected expenditures. Medical homes are generally more limited in their ability to bear financial risk than other Entities because they tend to be smaller and predominantly include primary care practitioners, whose revenues are a smaller fraction of the beneficiaries' total cost of care than those of other eligible clinicians. Moreover, Medicaid medical homes serve low income populations and those with significant health disparities; due to the method of payment for care for these populations, Medicaid medical home practices often have relatively low revenues. Lastly, Medicaid Medical Home Models to date have not required participants to bear substantial downside risk, and including such a requirement under this program would create a significant challenge for medical homes to serve their patients.

We seek comment on the proposed financial risk standard set forth for Medicaid Medical Home Models and on alternative standards that would be consistent with the statute and could achieve our stated goals. We also seek comment on types of financial risk arrangements that may not be clearly captured in this proposal.

(b) Nominal Amount of Risk

When an Other Payer APM risk arrangement meets the proposed financial risk standard, we would then consider whether the risk is of a more than nominal amount such that it meets this nominal risk standard. Similar to the financial risk portion of this assessment, we propose to adopt a generally applicable nominal amount standard for Other Payer Advanced APMs and a unique nominal amount standard for Medicaid Medical Home Models.

We propose to measure three dimensions of risk to determine whether a model meets the nominal amount standard: (a) Marginal risk, which is a common component of risk arrangements—particularly those that involve shared savings—that refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under an Other Payer APM; (b) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (c) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under an Other Payer APM. An example of marginal risk within an Other Payer APM could be set up in a manner similar to the Shared Savings Program, where an ACO that has a sharing rate, or marginal rate, of 50 percent and exceeds its benchmark (expected expenditures) by $1 million would be liable for $500,000 of those losses. The marginal risk could also vary with the amount of losses.

When assessing whether an Other Payer APM meets the marginal and total risk portions of the nominal risk standard, we would use the same approach we proposed to use with respect to APMs. Specifically, to determine whether an Other Payer APM satisfies the total risk portion of the nominal risk standard, we would identify the maximum potential payment an APM Entity could be required to make as a percentage of the expected expenditures under the Other Payer APM. If that percentage exceeded the required total risk percentage, then the arrangement would satisfy the total risk portion of the nominal risk standard.

To determine whether an Other Payer APM satisfies the marginal risk portion of the nominal risk standard, we would examine the payment required under the Other Payer APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We propose that we would require that this percentage exceed the required marginal risk percentage regardless of the amount by which actual expenditures exceeded expected expenditures, with two exceptions.

First, we propose a maximum allowable "minimum loss rate" (MLR) of 4 percent in which the payment required by the Other Payer APM could be smaller than the nominal amount standard would otherwise require when actual expenditures exceed expected expenditures by less than 4 percent; this exception accommodates Other Payer APMs that include zero risk with respect to small losses but otherwise satisfy the marginal risk standard. We also propose a process through which CMS could determine that a risk arrangement with an MLR higher than 4 percent could meet the nominal amount standard, provided that the other portions of the nominal risk standard are met. In determining whether such an exception would be appropriate, CMS would consider: (1) Whether the size of the attributed patient population is small; (2) whether the relative magnitude of expenditures assessed under the Other Payer APM is particularly small; and (3) in the case of test of limited size and scope, whether the difference between actual expenditures and expected expenditures would not be statistically significant even when actual expenditures are 4 percent above expected expenditures. We note that CMS would grant such exceptions rarely, and CMS would expect APMs considered for such exceptions to demonstrate that a sufficient number of APM Entities are likely to incur losses in excess of the higher MLR. In other words, the potential for financial losses based on statistically significant expenditures in excess of the benchmark remains meaningful for participants.

Second, we propose that the payment required by the Other Payer APM could be smaller when actual expenditures exceed expected expenditures by enough to trigger a payment greater than or equal to the total risk amount required under the nominal amount standard (as specified in Table 40). This exception ensures that the marginal risk requirement does not effectively require Other Payer APMs to incorporate total risk greater than the amount required by the total risk portion of the standard in order to become Other Payer Advanced APMs.

In evaluating both the total and marginal risk portions of the nominal amount standard, we would not include any payments the APM Entity or its participating providers would make to the other payer if actual expenditures exactly matched expected expenditures. In other words, payments made to the other payer outside the risk arrangement related to expenditures would not count toward the nominal risk standard. This requirement ensures that perfunctory or pre-determined payments do not supersede incentives for improving efficiency. For example, an Other Payer APM that simply requires an APM Entity to make a payment equal to 5 percent of the Other Payer APM benchmark at the end of the year, regardless of actual expenditure performance, would not satisfy the nominal amount standard.

Finally, like the Advanced APM criterion described in section II.F.4.b.(4) of this preamble, the amounts described in this section need not take a shared savings structure in which financial risk increases smoothly based on the amount by which an Other Payer Advanced APM Entity's actual expenditures exceed expected expenditures. The risk arrangement must be tied to expenditures, but the amount of that risk does not have to be directly proportional to expenditures. For instance, an APM Entity could be required to pay the payer a flat amount or an amount tied to the number of attributed beneficiaries in the case of exceeding an expenditure benchmark, provided that these amounts are otherwise structured in a way that satisfies the nominal amount standard.

(i) Generally Applicable Other Payer Advanced APM Nominal Amount Standard

Except for risk arrangements described under the Medicaid Medical Home Standard in paragraph (ii) below, we propose that for an Other Payer APM to meet the nominal amount standard the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and total potential risk must be at least four percent of the expected expenditures.

Other Payer APM arrangements with less than 30 percent marginal risk would not meet the nominal amount standard. We believe that meaningful risk arrangements can be designed with marginal risk rates of greater than 30 percent. Any marginal risk below 30 percent creates scenarios in which the total risk could be very high, but the average or likely risk for an Other Payer APM Entity would actually be very low.

Table 40 summarizes the generally applicable nominal amount standard.

TABLE 40: Amounts of Risk Sufficient for Other Payer Advanced APMs to Meet the Nominal Amount Standard

Marginal Risk	Maximum Potential Risk Must At Least Be the Following
<30%	N/A
30-100% of spending in excess of expected expenditures	4% of Other Payer expected expenditures

In establishing the proposed criteria for Other Payer Advanced APMs, we are keeping the approach to nominal risk as consistent as possible with the approach for the proposed Advanced APM criteria as described in section II.F.4.b.(4) of this preamble. The statute specifies that the Other Payer Advanced APM Entity must bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures. We believe it is important, to the extent possible and consistent with the statute, to adopt consistent financial risk standards with the Advanced APM standard as described in section II.F.4.b.(3) in this preamble, so that eligible clinicians can base their decisions on participation in these Other Payer APMs on a consistent set of criteria. The Advanced APM financial risk section of this preamble, II.F.4.b.(3) describes the process by which we arrived at the proposed values.

For Medicaid APMs we propose the same standard as for Other Payer APMs. However, we recognize that Medicaid practitioners may be less able to bear substantial financial risk because they are generally reimbursed at lower payment rates, and they serve low-income populations and those with significant health disparities. Therefore, we seek comment and supporting evidence on whether the proposal offered identifies the appropriate amounts of nominal risk for Medicaid APMs.

(ii) Medicaid Medical Home Model Nominal Amount Standard

For Medicaid Medical Home Models, we propose that the minimum total annual amount that an APM Entity must potentially owe or forego to be considered an Other Payer Advanced APM must be at least:

- In 2019, 4 percent of the APM Entity's total revenue under the payer.
- In 2020 and later, 5 percent of the APM Entity's total revenue under the payer.

We believe that because few Medicaid Medical Homes have experience with financial risk, and because they tend to be smaller in size than other APM Entities, we should not include a potentially excessive nominal amount for such entities in the first year of the program. We have also taken into account that the MACRA explicitly highlights Medical Home Models, generally, for special treatment under the Quality Payment Program. We have less information on Medicaid Medical Home Models and their performance to date compared to our information on Medical Home Models. Medicaid Medical Home Models are still developing, and we believe the introduction of a nominal amount standard that is not currently widely represented in the marketplace should be approached in a measured manner. We therefore believe that the unique characteristics of Medicaid Medical Home Models warrant the application of a nominal amount standard that reflects these differences, and statute provides us with the flexibility to make such a distinction.

We seek comment on all of the proposed nominal amount standards. We also seek comment on the potential inclusion of a marginal risk amount in the standard and the extent to which it is applicable.

(c) Capitation

We propose that full capitation risk arrangements would meet this Other Payer Advanced APM financial risk criterion. We propose that for purposes of this rulemaking, a capitation risk arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made to an APM Entity for services furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. Our rationale for this policy is the same as the rationale on capitation for Advanced APMs described in section II.F.4.b.(3) of this preamble. As such, we reiterate that capitation should not simply be a cash flow mechanism. We also reiterate that capitation arrangements qualifying under the financial risk standard must be structured to directly hold the provider—or the entity to which the provider has assigned their billing—accountable.

We seek comment on our proposal for categorical definition of Other Payer APM capitation risk arrangements as meeting the financial risk criterion for Other Payer Advanced APMs, and on our proposed definition of a capitation risk arrangement. We also seek comment on other types of arrangements that may be suitable for such treatment for purposes of this financial risk criterion.

(d) Criteria Comparable to Expanded Medical Home Model

In accordance with sections 1833(z)(2)(B)(iii)(II)(cc)(BB) and (C)(iii)(II)(cc)(BB) of the Act, we propose that Medicaid Medical Home Models that meet criteria comparable to a Medical Home Model expanded under section 1115A(c) of the Act would meet the Other Payer Advanced APM financial risk criterion. We propose that CMS will specify in subsequent rulemaking the criteria of any Medical Home Model that is expanded under section 1115A(c) of the Act that will be used for purposes of making this comparability assessment. We believe that the expanded Medical Home Model criteria can only be used for comparison when a Medical Home Model is, in fact, expanded as described in section II.F.4.b.(6) of this preamble, not merely by satisfying the expansion criteria under section 1115A(c) of the Act. If no such Medical Home Model has actually been expanded under section 1115A(c) of the Act, we would not have any criteria for comparison. In the absence of any expanded Medical Home Model to which we could draw comparisons, Medicaid Medical Home Models must meet the financial risk criterion through the other provisions (the financial risk and nominal amount standards) in order to be an Other Payer Advanced APM. We seek comment on how to determine the criteria of an expanded Medical Home Model that could be used for comparison, and on how similar the Medicaid Medical Home Model criteria must be to the expanded Medical Home Model criteria in order to be considered "comparable."

(7) Medicare Advantage (MA)

We received multiple comments on the MIPS and APMs RFI requesting that participation in Medicare Advantage be credited as participation in Advanced APMs. We recognize that many eligible clinicians participating in Medicare Advantage may offer high-value care to Medicare beneficiaries enrolled in such plans.

With respect to the APM Incentive Payment, section 1833(z)(1)(A) of the Act clearly states that the APM Incentive Payment is based on payments for Part B for covered professional services (which are made under the Medicare Physician Fee Schedule) and which do not include payments for services furnished to Medicare Advantage enrollees. For QP determination calculations, we believe it is important to note that APMs may involve Medicare Advantage plans and payers other than Medicare. Under the All-Payer Combination Option for QP determinations, eligible clinicians and Advanced APM Entities can meet the QP threshold based in part on payment amounts or patients counts associated with Medicare Advantage plans and other payers, provided that such arrangements meet the criteria to be considered Other Payer Advanced APMs. However, under sections 1833(z)(2)(A), (2)(B)(i), and (3)(B)(i) of the Act, such Medicare Advantage and other payer payments cannot be included in the QP determination calculations under the Medicare Option, which requires that we only consider payment amounts or patient counts for Medicare Part B covered professional services. Regardless of which option—Medicare or All-Payer Combination—is used to determine that an eligible clinician is a QP for a year, the APM Incentive Payment calculation will only be based upon payments for Medicare Part B covered professional services, which does not include payments for services furnished to Medicare Advantage enrollees.

We recognize that Medicare Advantage contracts can include financial risk as well as quality performance standards and certified EHR and other health IT requirements that support high-value care. We propose to evaluate payment arrangements between eligible clinicians, APMs Entities and MA plans as Other Payer APMs and according to the proposed Other Payer Advanced APM criteria. In the assessment of MA plans with respect to the Other Payer Advanced APM criteria, it is important to note that the requirements refer to aspects of the payment arrangement between the MA plan and the participating APM Entity, and this includes the criterion for bearing more than a nominal amount of financial risk. To qualify as an Other Payer Advanced APM, there must be a financial risk component. We would not consider an arrangement where the MA plan meets the CEHRT and quality measures criteria outlined in this proposed rule, but pays the APM Entity on a fee-for-service basis, to be an Other Payer Advanced APM because there is no risk connected to actual cost of care exceeding projected cost of care. Because this arrangement would not be an Other Payer Advanced APM, it would not be assessed for the purposes of determining QPs. In addition, the financial relationship between CMS and the MA plan—even if the relationship is part of a APM—is not relevant to this assessment because there would not be a direct payment arrangement between CMS and the APM Entities or eligible clinicians.

We also received comments on the MIPS and APMs RFI expressing concern that the distribution of APM Incentive Payments could disadvantage Medicare Advantage plans relative to Medicare FFS by changing payment rates for health plans in a given area based on the aggregate APM incentive amounts paid to eligible clinicians in that area. APM Incentive Payments will be lump-sum payments made under Medicare Part B, but outside of the claims payment system. Medicare Advantage rates are set through a separate process, and payment policies for 2019 will be addressed in the Advance Notice and Rate Announcement for that program.

c. Calculation of All-Payer Combination Option Threshold Score

(1) Submission of Information for Other Payer Advanced APM Determination and Threshold Score Calculation

We propose that APM Entities and/or eligible clinicians must submit certain information for CMS to assess whether other payer arrangements meet the Other Payer Advanced APM criteria and to calculate Threshold Scores a QP determination under the All-Payer Combination Option. For CMS to make QP determinations at the individual eligible clinician level in the specified exception cases described in section II.F.5 and II.F.6 of this preamble, either the Advanced APM Entity or the eligible clinician may submit this information with respect to the individual eligible clinician. If we do not receive sufficient information to complete our evaluation of the other payer arrangement and perform the QP threshold calculation, we would not evaluate the eligible clinicians under the All-Payer Combination Option.

We propose that submissions by APM Entities and/or eligible clinicians must include at least sufficient information for CMS to determine whether the payment arrangement meets the Other Payer Advanced APM criteria described in this section. To make the QP determination using the All-Payer Combination Option, submissions must include specific payment and patient numbers for each payer from whom the eligible clinician has received payments during the QP Performance Period, in order to calculate the Advanced APM Entity eligible clinician group's or individual eligible clinician's Threshold Score. We propose that—by a date and in a manner specified by CMS—the following data must be submitted to CMS for consideration under the All-Payer Combination Option: (1) The payment amounts and/or number of patients furnished any service through each Other Payer Advanced APM for each payer; and (2) the sum of their total payment amounts and/or number of patients furnished any service from each payer.

CMS will ask each payer to attest to the accuracy of all submitted information including the reported payment and patient data. Contracts may be subject to audit by CMS. We propose that if a payer does not attest to the accuracy of the reported payment and patient data, these data will not be assessed under the All-Payer Combination Option. However, we recognize that such a requirement leaves eligible clinicians dependent on a payer over which they may have limited control. We therefore seek comment on alternatives to requiring payer attestation, such as addressing the scope and intensity of audits to verify the submitted data. For Advanced APM Entities and eligible clinicians participating in Medicaid, CMS will initiate a review and determine in advance of the QP determination period the existence of Medicaid Medical Home Models and Medicaid APMs based on information obtained from state Medicaid agencies and other authorities, such as professional organizations or research entities. We seek comment regarding how such a review and determination could be conducted.

Detailed guidance on implementing data collection for Calculation of the All-Payer Combination Option Threshold Score will be issued prior to 2019.

(1) Use of Methods

CMS may apply one or both of two different methods—using payment amounts or patient counts—to arrive at an eligible clinician's Threshold Score. CMS will compare the Threshold Score against the relevant QP Threshold or Partial QP Threshold to determine an eligible clinician's QP status for the year.

We propose that CMS would calculate Threshold Scores for eligible clinicians in an Advanced APM Entity under both the payment amount and patient count methods for each QP Performance Period. We also propose that CMS would assign QP status using the more advantageous of the Advanced APM Entity's two scores.

We believe that both the payment amount and patient count methods should be considered in order to produce Threshold Scores. As the two calculations differ there may be cases in which Threshold Scores vary enough that different QP determinations could result depending on which is used. In such an event, we do not believe that prioritizing the Threshold Score using one calculation over the other would yield an appropriate, non-arbitrary result. By using the greater of the Threshold Scores achieved, we hope to promote simplicity in QP determinations and to maximize the number of eligible clinicians that attain QP status each year. We seek comment on the use of the payment and patient count methods for the All-Payer Combination Option.

(2) Excluded Payments

Section 1833(z)(2)(B)(ii)(I) and (C)(ii)(I) of the Act specifies that the calculation under the All-Payer

Combination Option is based on the sum of both payments for Medicare Part B covered professional services and, with certain exceptions, all other payments, regardless of payer. We propose that we will include such "all other" payments in the numerator and the denominator, and we will exclude payments as specified in the statute. We also propose to exclude patients associated with these excluded payments from the patient count method.

The statue excludes payments made:

- By the Secretary of Defense for the costs of Department of Defense health care programs;
- By the Secretary of Veterans Affairs for the costs of Department of Veterans Affairs health care programs; and
- Under Title XIX in a state in which no Medicaid Medical Home Model or APM is available under the state plan.

We propose that title XIX payments or patients would be excluded in the numerator and denominator for the QP determination unless: (1) A state has at least one Medicaid Medical Home Model or Medicaid APM in operation that is determined to be an Other Payer Advanced APM; and (2) the relevant Advanced APM Entity is eligible to participate in at least one of such Other Payer Advanced APMs during the QP Performance Period, regardless of whether the Advanced APM Entity actually participates in such Other Payer Advanced APMs. This will apply to both the payment amount and patient count methods. We believe this Medicaid exclusion avoids penalizing eligible clinicians who do not have the possibility of participation in an Other Payer Advanced APM under Medicaid. We believe that failing to exclude such payments and/or patients would unduly disadvantage potential QPs by inflating denominators based on circumstances beyond their control. For example, if a state's Medicaid Medical Home Model is determined to be an Other Payer Advanced APM and is operated on a statewide basis, Medicaid payments will be included in the denominator for all eligible clinicians in that state assessed under the All-Payer Combination Option. However, if the state operates such an Other Payer Advanced APM at a sub-state level, and eligible clinicians who do not practice in the geographic area where the Medicaid Medical Home Model is available are not eligible to participate, Medicaid payments would not be included in such eligible clinicians' QP calculations. We will more fully develop the approach to identify Medicaid Medical Home Models and Medicaid APMs, as well as eligible clinician eligibility to participate in them, through subsequent rulemaking.

We seek comment on our proposals to determine exclusions and on how we could account for eligible clinician participation in Medicaid APM or Medicaid Medical Home Models, such as pilots where participation may be intentionally limited by the state.

(3) Payment Amount Method

We propose to calculate an All-Payer Combination Option Threshold Score for eligible clinicians in an Advanced APM Entity using the payment amount method, which would then be compared to the relevant QP Payment Amount Threshold and Partial QP Payment Amount Threshold to make a QP determination.

(a) Threshold Score Calculation

(i) In General

We propose to calculate the All-Payer Threshold Score for eligible clinicians in an Advanced APM Entity (or an eligible clinician that participates in multiple APMs, as this exception is discussed above) by dividing the value described under paragraph (ii) by the value described under paragraph (iii). This calculation would result in a percent value Threshold Score that CMS would compare to the QP Payment Amount Threshold and the Partial QP Payment Amount Threshold to determine the QP status of the eligible clinicians for the payment year. The calculations occur in two steps because there is a Medicare QP Threshold and an All-Payer QP Threshold. The formula for determining the payment Threshold Score is: Threshold Score = A/B, where:

A = The numerator value under paragraph (ii) below
B = The denominator value under paragraph (iii) below

(ii) Numerator

We propose that the numerator would be the aggregate of all payments from all other payers, except those excluded under sections 1833(z)(2)(B)(ii)(I) and (C)(ii)(I) of the Act, to the Advanced APM Entity's eligible clinicians—or the eligible clinician in the event of an individual eligible clinician assessment—under the terms of all Other Payer Advanced APMs during the QP Performance Period. For example, if a beneficiary is attributed to an ACO and sees a clinician outside that ACO, payments made to the non-ACO clinician would not count towards this numerator, even if the ACO is an Other Payer Advanced APM. Medicare Part B covered professional services will be calculated under the All-Payer Combination Option in the same manner as it is for the Medicare Option.

(iii) Denominator

We propose that the denominator would be the aggregate of all payments from all other payers, except those excluded under sections 1833(z)(2)(B)(ii)(I) and (C)(ii)(I) of the Act, to the Advanced APM Entity's eligible clinicians—or the eligible clinician in the event of an individual eligible clinician assessment—during the QP Performance Period. The portion of this amount that relates to Medicare Part B covered professional services will be calculated under the All-Payer Combination Option in the same manner as it is for the Medicare Option.

(b) Examples of Payment Amount Threshold Score Calculation

In this example, an Advanced APM Entity participates in a Medicare ACO initiative, a commercial ACO arrangement, and a Medicaid APM. Each of the APMs is determined to be an Advanced APM. In the QP Performance Period for payment year 2021 (proposed in this proposed rule to be 2019), the Advanced APM Entity receives the following payments:

TABLE 41: All-Payer Combination Option Example 1

Payer	Payments through ACO	Total Payments from Applicable Payer	Threshold Score
Medicare*	300,000	1,000,000	30%
Commercial	300,000	500,000	60%
Medicaid	80,000	100,000	80%
Total	680,000	1,600,000	43%

*For Medicare Part B payments, the amount used for the All-Payer Combination Option will be the same as the amount tied to attribution-eligible beneficiaries used in the denominator of the calculation under the Medicare Option.

In Table 41, the Advanced APM Entity meets the minimum Medicare threshold (30% >25%). However, it falls short of the QP Payment Amount Threshold (43% <50%). In this case, the Advanced APM Entity would meet the Partial QP Payment Amount Threshold (43% >40%).

Another Advanced APM Entity in the same year receives the following payments:

TABLE 42: All-Payer Combination Option Example 2

Payer	Payments through ACO	Total Payments from Applicable Payer	Threshold Score
Medicare*	200,000	500,000	40%
Commercial	400,000	500,000	80%
Medicaid	100,000	150,000	67%
Total	700,000	1,150,000	61%

*For Medicare Part B payments, the amount used for the All-Payer Combination Option will be the same as the amount tied to attribution-eligible beneficiaries used in the denominator of the calculation under the Medicare Option.

In Table 42, the Advanced APM Entity meets the minimum Medicare threshold (40% >25%). It also exceeds the QP Payment Amount Threshold (61% >50%). In this case, the eligible clinicians in the Advanced APM Entity would become QPs.

We seek comment on the payment amount method described in this proposal and any potential alternative approaches.

(4) Patient Count Method

We propose to calculate a Threshold Score for the eligible clinician group in an Advanced APM Entity—or eligible clinician in the exception situations under sections II.F.5 and II.F.6 of this preamble—using the patient count method, which would then be compared against the relevant QP Patient Count Threshold and Partial QP Patient Count Threshold to determine the QP status of an eligible clinician for the year based on the higher of the two values.

(a) Threshold Score Calculation

(i) In General

We propose that the Threshold Score calculation for the patient count method would include patients for whom the eligible clinicians in an Advanced APM Entity furnish services and receive payment under the terms of an Other Payer Advanced APM, with certain exceptions as outlined in the previous section. This calculation would result in a percent value Threshold Score that CMS would compare to the QP Patient Count Threshold and the Partial QP Patient Count Threshold to determine the eligible clinicians' QP status for the payment year. The calculations occur in two steps as there is a Medicare Threshold requirement and an All-Payer Threshold requirement. The formula for determining the patient count Threshold Score is:

Threshold Score = A/B,

where:

A = The numerator value under paragraph (iii) below.

B = The denominator value under paragraph (iv) below.

(ii) Unique Patients

First, we propose that, like the Medicare Option, the patient count method under the All-Payer Combination Option would only count unique patients, with multiple eligible clinicians able to count the same patient. Similarly, we propose to count a single patient, where appropriate, in the numerator and denominator for multiple different Advanced APM Entities when counting the number of beneficiaries under this method section II.F.6 of this preamble. We also propose that CMS will not count any patient more than once for any single Advanced APM Entity. In other words, for each Advanced APM Entity, CMS will count each unique patient one time in the numerator, and one time in the denominator.

We believe that counting patients this way maintains integrity by preventing double counting of patients within an Advanced APM Entity while recognizing the reality that patients often have relationships with eligible clinicians in different organizations. We hope to avoid distorting patient counts for such overlap situations, especially in Advanced APM Entity-dense markets.

We seek comment on our proposal for counting patients and on alternative methods for counting beneficiary overlaps across Advanced APM Entities.

(iii) Numerator

We propose that the numerator would be the number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services that are included in the measures of aggregate expenditures used under the terms of all of their Other Payer Advanced APMs during the QP Performance Period, plus the patient count numerator for Advanced APMs. A patient would count in the non-Medicare portion of this numerator only if, as stated above, the eligible clinician furnishes services to the patient and receives payment(s) for furnishing those services under the terms of an Other Payer Advanced APM.

(iv) Denominator

We propose that the denominator would be the number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services under all non-excluded payers during the QP Performance Period.

(b) Examples of Patient Count Threshold Score Calculation

In the QP Performance Period for payment year 2021 (proposed to be 2019 under this proposed rule) the Advanced APM entity experienced the following patient counts:

TABLE 43: All-Payer Combination Option Example 3

Payer	Patients through ACO	Total Patients from Payer	Threshold Score
Medicare*	3,000	10,000	30%
Commercial	1,000	5,000	20%
Medicaid	800	1,000	80%
Total	4,800	16,000	30%

*For Medicare Part B patients, the amount used for the All-Payer Combination Option will be the same as the number of attribution-eligible beneficiaries used in the denominator of the calculation under the Medicare Option.

In Table 43, the Advanced APM Entity meets the minimum Medicare threshold (30% >20%). However, it falls short of the QP Patient Count Threshold (30% <35%). In this case, the Advanced APM Entity would meet the Partial QP Patient Count Threshold (30% >25%).

Another Advanced APM Entity in the same year experienced the following patient counts:

TABLE 44: All-Payer Combination Option Example 4

Payer	Patients through ACO	Total Patients from Payer	Threshold Score
Medicare*	2,000	5,000	40%
Commercial	4,000	5,000	80%
Medicaid	1,000	1,500	67%
Total	7,000	11,500	61%

*For Medicare Part B patients, the amount used for the All-Payer Combination Option will be the same as the number of attribution-eligible beneficiaries used in the denominator of the calculation under the Medicare Option.

In Table 44, the Advanced APM Entity meets the minimum Medicare threshold (40% > 20%). It also exceeds the minimum QP Patient Count Threshold (61% > 35%). In this case, the eligible clinicians in the Advanced APM Entity would become QPs.

We seek comment on the patient count method described above and any potential alternative approaches.

d. Submission of Information for Assessment Under the All-Payer Combination Threshold Option

Under sections 1833(z)(2)(B)(ii)(III) and (C)(ii)(III), an eligible clinician can only become a QP using the All-Payer Combination Option by providing the Secretary such information as is necessary for the Secretary to determine whether an Other Payer APM is an Other Payer Advanced APM and to determine the eligible clinician's Threshold Score under section II.F.7.c of this preamble. To be considered under the All-Payer Combination Option we propose that APM Entities or individual eligible clinicians must submit by a date and in a manner determined by CMS: (1) Payment arrangement information necessary to assess whether each Other Payer APM is an Other Payer Advanced APM, including information on financial risk arrangements, use of certified EHR technology, and payment tied to quality measures; and (2) for each Other Payer APM, the amounts of revenues for services furnished through the arrangement, the total revenues from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed projected expenditures), and the total numbers of patients furnished any service through the payer. CMS would then assess the characteristics of the Other Payer APMs to determine if they are Other Payer Advanced APMs and would notify the APM Entities and/or eligible clinicians of the Other Payer Advanced APM determinations based on their submissions. We propose further, that an Other Payer Advanced APM is required to have an outcome measure. If an Other Payer Advanced APM has no outcome measure, the Advanced APM Entity must attest that there is no applicable outcome measure on the MIPs list. CMS intends to establish specific requirements regarding the timing and manner of submission of such information through future rulemaking.

At this time, we seek comment from stakeholders on the specific types of payment arrangement information that would be necessary to assess whether an

Other Payer APM is an Other Payer Advanced APM, and the format in which CMS could reasonably expect to receive this information. We seek comment on the level of detail which CMS should require, and whether certain pieces of information would be most easily submitted directly from individual eligible clinicians or from an APM Entity. We also seek comment on the timing of when CMS could expect to receive this information from individual eligible clinicians and Advanced APM Entities for a performance year. In addition, we seek comment on the proposed requirement that an Other Payer Advanced APM must have an outcome measure.

We seek comment on the possibility of receiving information on Other Payer APMs and their participants directly from other payers in order to minimize reporting burden for APM Entities and eligible clinicians. We seek comment on the extent to which collecting voluntary submissions of data from other payers could reduce burden and increase program integrity through more accurate determinations of QP status based on payment or patient threshold calculations for Other Payer Advanced APMs. Likewise, we seek comment on the extent to which such data collection is operationally feasible or could infringe upon other payers' interests in maintaining the confidentiality of their business practices.

In addition, we propose to make early Other Payer Advanced APM determinations on other payer arrangements if sufficient information is submitted at least 60 days before the beginning of a QP Performance Period. This would allow CMS to offer eligible clinicians advance notice of their prospects of achieving QP status in the event they are assessed under the All-Payer Combination Option. This early determination would be considered final for the QP Performance Period based on the Other Payer APM information submitted. If new information is submitted based on a change in the Other Payer APM during the QP Performance Period, the initial determination could be subject to review and revision. We also propose that, to the extent permitted by federal law, CMS would maintain confidentiality of certain information that the Advanced APM Entities and/or eligible clinicians submit regarding Other Payer Advanced APM status in order to avoid dissemination of potentially sensitive contractual information or trade secrets. We propose that, unlike our proposal for Advanced APM determinations, the Other Payer Advanced APM determinations would be made available directly to participating APM Entities and eligible clinicians rather than through public notice, and we would explain how and within what timeframes such notifications will occur in subregulatory guidance. CMS may consider publicly releasing information on Other Payer Advanced APMs on the CMS Web site with general and/or aggregate information on the payers involved and the scopes of such agreements.

We seek comment on the proposed timing and method of feedback to Advanced APM Entities and eligible clinicians regarding the status of Other Payer Advanced APMs for which they have submitted information and on the proposed early determination process and the ability of Advanced APM Entities and eligible clinicians to submit sufficient information prior to the beginning of a QP Performance Period. We also seek comment on the types of information that contain potentially sensitive information.

The information submitted to determine whether an eligible clinician is a QP under the All-Payer Combination Option may be subject to audit, and eligible clinicians and Advanced APM Entities will be required to maintain copies of any supporting documentation. If an audit reveals a material discrepancy in the information submitted to CMS, and such discrepancy affected the eligible clinician's QP status, the APM Incentive Payment may be recouped. Providing false information may reflect a false claim subject to investigation and prosecution. We may provide further details on the audit and recoupment process under the All-Payer Combination Option in future rulemaking.

8. APM Incentive Payment

The APM Incentive Payment is specified under section 1833(z)(1) of the Act.

a. Amount of the APM Incentive Payment

This section describes our proposal for calculating the amount of the APM Incentive Payment and accounts for the specific scenarios outlined under sections 1833(z)(1)(A)(i) and 1833(z)(1)(A)(ii) of the Act. This section also describes the process by which CMS proposes to disburse these APM Incentive Payments to QPs.

In accordance with section 1833(z)(1)(A) of the Act, CMS will make an APM Incentive Payment for a year to eligible clinicians that achieve QP status for the year during years 2019 through 2024. In accordance with the statute, we propose that this APM Incentive Payment shall be equal to 5 percent of the estimated aggregate amounts paid for Medicare Part B covered professional services furnished by the eligible clinician from the preceding year across all billing TINs associated with the QP's NPI.

(1) Incentive Payment Base Period

The incentive payment base period is the range of dates that will be used to calculate the estimated aggregate payment amounts for the year preceding the QP payment year that will serve as the basis for the incentive payment. Section 1833(z)(1)(A) of the Act states that in calculating the amount that is equal to 5 percent of the estimated aggregate payment amounts for Medicare Part B covered professional services under this part for the preceding year, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. We believe this provision gives CMS flexibility in determining the incentive payment base period. We propose to use the full calendar year prior to the payment year as the incentive payment base period from which to calculate the estimated aggregated payment amounts.

When determining the time period for the incentive payment base period, we considered using a partial calendar year and a completion factor to forecast and account for the remainder of claims that would be billed during the remainder of the calendar year. However, there are instances where eligible clinician practice patterns change during a given period of time. For example, an eligible clinician may begin practicing, retire, change practice locations, or switch between full-time and part-time; or there could be seasonal fluctuations in an eligible clinician's practice. Given the possible variability in billings and payments over a calendar year, we believe an incentive payment base period of less than one year would produce a less accurate estimated aggregated payment amount and could potentially disadvantage some eligible clinicians based on the circumstances of their practice in a given year.

Using a complete calendar year of claims would allow for the most accurate representation of the covered professional services delivered by each eligible clinician, which we believe outweighs a modest potential delay in making the APM Incentive Payment. We seek comment on our proposal to use the entire preceding calendar year as the incentive payment base period.

(2) Timeframe of Claims

Section 1833(z)(1)(A) of the Act directs CMS to make the APM Incentive Payment in a lump sum on an annual basis "as soon as practicable." We believe that, in implementing this provision, it is important to balance the desire for accuracy in the data used to calculate the APM Incentive Payment with the desire to expedite the payments so that the APM Incentive Payments are made in an appropriate and timely manner.

We propose to calculate the APM Incentive Payment based on data available 3 months after the end of the incentive payment base period in order to allow time for claims to be processed. For example, for the 2019 payment year, we would capture claims submitted with dates of service from January 1, 2018 through December 31, 2018 and processing dates of January 1, 2018 through March 31, 2019. We believe that 3 months of claims run-out is sufficient to conduct the APM Incentive Payment calculations in an accurate and timely manner. This methodology is consistent with the claims run-out timeframes used for reconciliation payments in several current APMs, such as the Shared Savings Program, the Pioneer and Next Generation ACO Models, and CEC. We seek comment on the potential use of a completion factor. We note that several current APMs apply the 3 month claims run-out in conjunction with a completion factor. However, where a completion factor may be appropriate for payments based on claims submitted by groups of providers and suppliers that may be billing under multiple TINs, we believe that with payments based on individual eligible clinician claims, categorical variability in claims completion across type of eligible clinicians would cause inequitable results.

We recognize that by pulling claims 3 months after the end of the performance year to conduct reconciliation, we would not have a complete claims run-out, especially for the later months of the year. We considered instead proposing a 6 month of claims run-out. On average, 99.3 percent of Medicare claims are processed within 3 months after the end of a calendar year, and 99.8 percent of claims are processed within 6 months after the end of a calendar year. We concluded that the benefit of making the incentive payments 3 months earlier outweighed the benefit of an additional 3 months of processed claims, since the difference in claims completion is extremely small. We also believe that our proposal provides an additional incentive for timely submission of claims at the end of the year because claims for services furnished during the incentive payment base period that are not submitted and processed within this 3 month run-out would not be considered in the incentive payment amount calculations.

We also considered our regulations at § 424.44 and the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 1, Section 70, stating that Medicare claims can be submitted no later than one calendar year from the date of service. We considered waiting for the full claims run-out 12 months after the end of the performance year, but were concerned that this approach would significantly delay the timing of the incentive payments and possibly dilute their effect as a reward for eligible clinician decisions to participate in APMs. We also believe that such a significant delay would not be consistent with the statutory intent of making payments as soon as practicable.

In summary, for the incentive payment base period we propose to use a complete calendar year of claims with 3 months of claims run-out from the end of the calendar year. We believe our proposed approach balances our goals of providing incentive payments in a reasonable timeframe while being able to account for the vast majority (on average, 99.3 percent of claims for) covered professional services. Given these parameters, we estimate that incentive payments could be made approximately 6 months after the end of the incentive payment base period, or roughly mid-way through the payment year. However, we propose that the APM Incentive Payment would be made no later than one year from end of the incentive payment base period. We do not propose to set a specific deadline mid-way during the payment year because we believe doing so could pose operational risks in the event that 6 months is impracticable in a given year for reasons that CMS cannot predict. We seek comment on our proposed timing of the incentive payment base period.

(3) Treatment of Payment Adjustments in Calculating the Amount of APM Incentive Payment

Part B covered professional services under the Medicare PFS are currently subject to several statutory provisions that are geared towards improving quality and efficiency in service delivery. Eligible clinicians are subject to payment adjustments under: The Medicare EHR Incentive Program for Eligible Professionals (MU), the PQRS, and the VM. Beginning in 2019, the MIPS adjustment, as described in section II.E.5, will replace payment adjustments under the MU, PQRS, and VM for all MIPS eligible clinicians. These special payment provisions directly adjust the payment amount that eligible clinicians receive under the PFS. In contrast, we consider the APM Incentive Payment to be separate from, and, as indicated under section 1833(z)(1)(A) of the Act, in addition to the amount of payments made for covered professional services under the Medicare PFS.

We propose to exclude the MIPS, VM, MU and PQRS payment adjustments when calculating the estimated aggregate payment amount for covered professional services upon which to base the APM Incentive Payment amount. For example, a QP who receives an upward fee adjustment during 2018 in VM would not see that adjustment reflected in the estimated aggregate payment amount for covered professional services used to calculate his or her APM Incentive Payment in 2019. Similarly, a QP who receives a downward fee adjustment during 2018 in VM would not see that amount reflected in the aggregate payment amount for the APM Incentive Payment.

We believe this proposed policy is most consistent with the specification in section 1833(z)(1)(A) of the Act that the APM Incentive Payment is based on the estimated aggregate payment amounts for "such" covered professional services for the preceding year, which refers to the Part B covered professional services furnished by the particular eligible clinician.

While we considered the alternative of including these performance-related payment adjustments in calculating the APM Incentive Payment, we are concerned that such a policy would create incentives that are not aligned with the intent of the APM Incentive Payment. As previously stated in our policy principles, we believe that the APM Incentive Payment is best viewed as a complementary reward for eligible clinicians that have a substantial degree of participation in the most advanced APMs and deliver high-value care, not an evaluation of their performance within the APM or in another statutorily required performance-based payment adjustment.

For example, the incentive payment base period for the 2019 payment year will be 2018, and any QP in payment year 2019 may have quality payment adjustments from the PQRS, MU, and VM payment provisions, which affect the amount of incentive payment for that year, in the incentive payment base period. The PQRS, MU, and VM payment adjustments will sunset at the end of 2018. In addition, in 2020 and later, eligible clinicians who were subject to MIPS in the previous performance year and become newly qualified as QPs may have MIPS quality payment adjustments during the base period affecting their APM Incentive Payment amounts for that period. We do not believe the intent of the APM Incentive Payment is to further magnify the currently existing and future payment adjustments because of overlapping time periods.

We also proposed in section II.F.6.b.(1) to account for payment adjustments in the QP determination process in the same manner as when calculating the amount of the APM Incentive Payment. If we were to include statutory payment adjustments when determining QP status, there could be situations where an eligible clinician could become a QP because of a positive payment adjustment amount, or conversely, there could be situations where an eligible clinician would not meet the QP threshold because of a negative payment adjustment. We believe that our proposal to not include payment adjustments when determining QP status for a year, or when calculating the amount of the APM Incentive Payment, allows CMS to assess all eligible clinicians on the same merits throughout the entire QP determination and APM Incentive Calculation process. We do not believe the intent of the statute was to enhance or negate an eligible clinician's opportunity to become a QP in a given performance year, or to enhance or negate the amount of APM Incentive Payment a QP receives, based on factors that are extraneous to APM participation.

We seek comment on this proposed approach to coordinating the various Medicare Physician Fee Schedule payment adjustments when calculating the amount of the APM Incentive Payment.

(4) Treatment of Payments for Services Paid on a Basis Other Than Fee-For-Service

We recognize that many APMs use incentives and financial arrangements that differ from usual fee schedule payments. Section 1833(z)(1)(A)(i) of the Act requires us to establish policies for payments that are made to an Advanced APM Entity rather than directly to the QP. Section 1833(z)(1)(A)(ii) of the Act requires us to establish policies for when payment is made on a basis other than fee-for-service. For the purposes of this proposed regulation, we place such payments into three categories: Financial risk payments, supplemental service payments, and cash flow mechanisms.

Financial risk payments are non-claims-based payments, based on performance in an APM when an APM Entity assumes responsibility for the cost of a beneficiary's care, whether it be for an entire performance year, or for a shorter duration of time, such as over the course of a defined episode of care. We note that in the context of categorizing these types of payments as "financial risk payments," we refer to payments that may be based on the cost of a beneficiary's care and do not necessarily limit these payments to financial arrangements that would require an APM Entity to accept downside risk. For instance, we would consider the shared savings payments to ACOs in all tracks of the Shared Savings Program to be financial risk payments. We would also consider net payment reconciliation amounts from CMS to an Awardee (or vice versa) under the BPCI Initiative, and reconciliation payments from CMS to a participant hospital or repayment amounts from a participant hospital to CMS under the CJR model to be examples of financial risk payments.

We propose to exclude financial risk payments such as shared savings payments or net reconciliation payments, when calculating the estimated aggregate payment amount. Financial risk payments are not for specific Medicare Part B covered professional services; rather they are for performance in an APM. Therefore, we believe their inclusion in the estimated aggregate payment amount would be inconsistent with the statutory language and our stated policy principles. In addition, the difficulty of disaggregating payments to individual QPs and the lagged timing of some financial risk payments creates significant policy and operational barriers that we do not believe are in line with our objective of making APM Incentive Payments in a timely manner.

Supplemental service payments are Medicare Part B payments for longitudinal management of a beneficiary's health, or for services that are within the scope of medical and other health services under Medicare Part B that are not separately reimbursed through the physician fee schedule. Often these are per-beneficiary per-month (PBPM) payments that are made for care management services or separately billable services that share the goal of improving quality of care overall, enabling investments in care improvement, and reducing Medicare expenditures for services that could be avoided through care coordination. For example, the OCM makes a per beneficiary Monthly Enhanced Oncology Services (MEOS) payment to practices for care management and coordination during episodes of care initiated by chemotherapy treatment.

We propose to determine on a case-by-case basis whether certain supplemental service payments are in lieu of covered services that are reimbursed under the PFS. In cases where payments are for covered services that are in lieu of services reimbursed under the PFS, those payments would be considered covered professional services and would be included in the APM Incentive Payment amounts. We propose to include a supplemental service payment in calculation of the APM Incentive Payment amount if it meets all of the following 4 criteria:

(1) Payment is for services that constitute physician services authorized under section 1832(a) of the Act and defined under section 1861(s) of the Act.

(2) Payment is made for only Part B services under the first criterion above, that is, payment is not for a mix of Part A and Part B services.

(3) Payment is directly attributable to services furnished to an individual beneficiary.

(4) Payment is directly attributable to an eligible clinician.

Table 45 provides an example of how a limited number of supplemental service payments in currently operating or recently announced APMs would be considered with respect to our proposed criteria. We further propose to establish a process by which we notify the public of the supplemental service payments in all APMs and identify the supplemental service payments that meet our proposed criteria and would be included in the APM Incentive Payment calculations. Similar to our proposal to announce Advanced APM determinations, we propose to post an initial list of supplemental service payments that would be included in our APM Incentive Payment calculations on the CMS Web site. As new APMs are announced, CMS would include its determination of whether an APM related supplemental service payment would be included in our APM Incentive Payment calculations, if applicable, in conjunction with the first public notice of the APM. We propose to update the list of supplemental service payments that would be included in our APM Incentive Payment calculations on an ad hoc basis, but no less frequently than on an annual basis.

We seek comment on this proposed approach to include certain supplemental service payments when calculating the basis for the amount of the APM Incentive Payment.

Specifically, we seek comment on our proposed criteria to include supplemental service payments in the basis for the APM Incentive Payment amounts, and our proposed method for announcing which supplemental service payments would be included in the basis for the APM Incentive Payment amounts.

TABLE 45: Limited examples of Supplemental Service Payment in current APMs

APM	Does Payment meet Criterion 1?	Does Payment meet Criterion 2?	Does Payment meet Criterion 3?	Does Payment meet Criterion 4?	Include Payment in APM Incentive Payment Calculations?
OCM MEOS Payment	Y	Y	Y	Y	Y
CPC Plus Care Management Fee (CMF)	Y	Y	Y	Y	Y
Medicare Care Choices Model PBPM payment	N	N	Y	Y	N
Million Hearts® Cardiovascular Disease Risk Reduction Model Cardiovascular Risk Assessment Payment	Y	Y	Y	Y	Y
Million Hearts® Cardiovascular Disease Risk Reduction Model Cardiovascular Care Management Fee	Y	Y	Y	Y	Y
Million Hearts® Cardiovascular Disease Risk Reduction Model Control Group Payment	N	N	Y	Y	N

Cash flow mechanisms involve changes in the method of payments for services furnished by providers and suppliers participating in an APM Entity. In themselves, cash flow mechanisms do not change the overall amount of payments. Rather, they change cash flow by providing a different method of payment for services. An example of a cash flow mechanism is the population-based payment (PBP) available in the Pioneer ACO Model and the Next Generation ACO Model. PBP provides ACOs with a monthly lump sum payment in exchange for a percentage reduction in Medicare fee-for-service payments to certain ACO providers and suppliers.

For expenditures affected by cash flow mechanisms, we propose to calculate the estimated aggregate payment amount using the payment amounts that would have occurred for Part B covered professional services if the cash flow mechanism had not been in place. For example, for QPs in an ACO receiving PBP with a 50 percent reduction in fee-for-service payments, we would use the amount that would have been paid for Part B covered professional services in the absence of the 50 percent reduction. Cash flow mechanisms represent a potential reallocation of dollars between eligible clinicians and entities for specific purposes related to care improvement. We do not believe that the presence of certain cash flow mechanisms should impact the APM Incentive Payment amount, and we do not intend for the APM Incentive Payment to influence the use or attractiveness of cash flow mechanisms in current and future APMs.

We recognize that new payment methods and financial arrangements may be developed that do not fit into these categories as described. For instance, in the recently announced CPC + Model, the supplemental service payments (that is, the CMFs) would meet all of our proposed criteria to be included in the APM Incentive Payment calculations. The CMFs are for Medicare Part B covered professional services, and the CMF payments will only cover Medicare Part B covered professional services. The CMF amounts will be risk adjusted based on each individual beneficiary's HCC risk scores; therefore these payments will be attributable to individual beneficiaries. Additionally, the attribution method in the CPC + Model uses a combination of the TIN/Individual NPI/Practice Address when attributing an individual beneficiary to a CPC Practice site. However, the CMF payments for attributed beneficiaries are aggregate payments is made to each CPC Practice Site. We recognize that throughout the course of a QP Performance Period more than one NPI may furnish covered professional services to an attributed beneficiary. If that occurs, more than one NPI could potentially receive the corresponding CMF for that eligible beneficiary. We do not believe it would be appropriate to count the same CMF for more than one NPI. Therefore, (assuming that the CPC + Model is deemed an Advanced APM and the APM Entity group achieves the QP threshold for a QP Performance Period), we could split the CMF amounts equally between the multiple NPIs, or we could develop a method to "assign" the NPI for which the CMFs would be counted in their APM Incentive Payment calculation based on the plurality of visits with that beneficiary.

We seek comment on the methods that CMS could use to allocate the supplemental service payments to individual NPIs in these types of scenarios in which payment for a supplemental service payment is made in the aggregate to an APM Entity.

We also recognize that payment methods and financial arrangements may evolve over time and would need to be addressed in future rulemaking. CMS seeks comment on the proposals for accounting for risk-based payments, supplemental service payments, and cash flow mechanisms when calculating the amount of APM Incentive Payment.

(5) Treatment of Other Incentive Payments in Calculating the Amount of APM Incentive Payments

Section 1833(z)(1)(D) of the Act specifies that CMS shall not include certain existing Medicare incentive payments in the calculation of the APM Incentive Payment. This includes payments made under section 1833 of the Act (subsections (m), (x), and (y)). Section 1833(m) of the Act describes the HPSA Physician Bonus Program. The HPSA Physician Bonus Program provides bonus payments to physicians for physicians' services furnished in geographic areas that are designated as of December 31 of the prior year by the HRSA as HPSAs under section 332 (a)(1)(A) of the PHS Act. The HPSA bonus payment is 10 percent of the Medicare Part B payment amount for the service; and this bonus is paid as a quarterly lump sum payment.

Subsection (x) describes the Primary Care Incentive Payment (PCIP) program. The PCIP payment amount was 10 percent of the payment amount for Medicare Part B primary care services furnished by primary care practitioners for whom primary care services accounted for at least 60 percent of their allowed fee-for-service charges in a prior qualification period. For purposes of the PCIP program, primary care practitioners were defined as those physicians with certain Medicare specialty codes and certain types of non-physician practitioners. The PCIP payment was made on a quarterly basis. This bonus payment expired under the statute on December 31, 2015.

Subsection (y) describes the HPSA Surgical Incentive Payment (HSIP). For major surgical procedures furnished by physicians with a primary specialty designation of "general surgeon" in HPSAs (under section 332(a)(1)(A) of the PHS Act), physicians received an additional 10 percent bonus payment in addition to the amount of payment that would otherwise be made. This additional payment was combined with any other HPSA payment outlined in 1833 of the Act, subsection (m), and was paid on a quarterly basis. This bonus payment expired under the statute on December 31, 2015.

Section 1833(z)(1)(D) of the Act also directs CMS not to include APM Incentive Payments when calculating payments made under section 1833 (subsections (m), (x), and (y)) of the Act. CMS considers the APM Incentive Payment to be separate from the incentive payments as previously discussed in this section and has established procedures to ensure that the APM Incentive Payment will not be included when calculating the amount of incentive payments made under section 1833 (subsections (m), (x), and (y)) of the Act.

(6) Treatment of the APM Incentive Payment in APM Calculations

Section 1833(z)(1)(C) states that the amount of the APM Incentive Payment shall not be taken into account for purposes of determining actual expenditures under an APM and for purposes of determining or rebasing any benchmarks used under the APM. As a lump sum payment, the APM Incentive Payments will be made outside of the Medicare claims processing system. Current APMs, such as the Medicare ACO initiatives and the CJR model, have established procedures for ensuring that lump sum payments from other APMs are accounted for when they do their APM reconciliations and rebasing calculations. We anticipate that each APM will have in place a procedure to avoid counting APM Incentive Payments toward determining actual expenditures or rebasing any benchmarks under the APM.

b. Services Furnished Through CAHs, RHCs, and FQHCs

(1) Critical Access Hospitals (CAHs)

Eligible clinicians who furnish services at Critical Access Hospitals (CAHs) that have elected to be paid for outpatient services under section 1834(g)(2)(B) of the Act (Method II) will be eligible to become QPs and receive the APM Incentive Payment if they are part of an Advanced APM Entity. As stated in section II.F.6.d.(1) of this proposed rule, professional services furnished at a Method II CAH are considered "covered professional services" because they are furnished by an eligible clinician and payment is based on the Medicare Physician Fee Schedule. Therefore, the APM Incentive Payment would be based on the amounts paid for those services attributed to the eligible clinician, as identified using the attending NPI included on a submitted claim, in the same manner as all other covered professional services.

For an eligible clinician who becomes a QP based on covered professional services furnished at a Method II CAH, we propose that the APM Incentive Payment would be made to the CAH TIN that is affiliated with the Advanced APM Entity. This proposal is consistent with how CMS proposes to make the APM Incentive Payment to eligible clinicians who practice at locations other than Method II CAHs. We seek comment on this proposal.

(2) Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

As explained in section II.F.6.d.(2) of this preamble, payment for services furnished by eligible clinicians in RHCs and FQHCs is not reimbursed under or based on the PFS. Therefore, professional services furnished in those settings would not constitute covered professional services under section 1848(k)(3)(A) of the Act and would not be considered part of the amount upon which the APM Incentive Payment is based. For eligible clinicians that practice in RHCs or FQHCs, this does not preclude the inclusion of payment amounts for covered professional services furnished by those eligible clinicians in other settings. This only excludes payments made for RHC and FQHC services furnished by the eligible clinicians. For example, an eligible clinician may practice at both an FQHC and with a separate physician group practice that receives payment under the PFS. If the eligible clinician becomes a QP under the methodologies described in II.F.6, whether based on their participation in an Advanced APM Entity that includes the FQHC as outlined in section II.F.6.d.(2) or based on their participation in an Advanced APM Entity that includes the separate physician group practice, or both, only the eligible clinician's payments for covered professional services at the separate physician group practice setting would form the basis amount for the APM Incentive Payment.

c. Payment of the APM Incentive Payment

(1) Payment to the QP

The APM Incentive Payment, as described in this section, will be made to QPs who are identified by their unique TIN/NPI combination as participants in an Advanced APM Entity on a CMS maintained list.

We received a number of comments on the MIPS and APMs RFI regarding the process by which we should make the APM Incentive Payment. One commenter suggested that we give QPs the opportunity to select where they want the APM Incentive Payment to be sent, while another suggested that we send payments directly to the individual eligible clinician. A number of commenters recommended that CMS make the APM Incentive Payments directly to the Advanced APM Entity. Additionally, some commenters noted that making payments directly to the Advanced APM Entity would allow Advanced APM Entities to fairly and accurately allocate incentive payments in accordance with the shared risk for individual eligible clinicians in the APM Entity. We thank the commenters for their feedback.

After consideration of these comments, we propose that for eligible clinicians that are QPs, CMS would make the APM Incentive Payment to the TIN that is affiliated with the Advanced APM Entity through which the eligible clinician met the threshold during the QP performance period. For both individual eligible clinicians and group practices, CMS uses the TIN as the billing unit. Earlier in this section, we proposed that the APM Incentive Payment would be calculated across all billing TINs associated with an NPI. Medicare has the ability to track all unique TIN/NPI combinations associated with an individual NPI, including which TINs are affiliated with an Advanced APM entity. We considered making separate payments for each TIN/NPI combination associated with the individual eligible clinician's APM Incentive Payment, similar to the current PQRS incentive payment program. Under the current PQRS incentive payment program, incentive payments are paid to the holder of the TIN, aggregating individual incentive payments for groups that bill under one TIN. For eligible clinicians who submit claims under multiple TINs, CMS groups claims by TIN for payment purposes and any incentive payments earned are paid to that specific TIN. As a result, an eligible clinician with multiple TINs who qualifies for the PQRS incentive payment under more than one TIN would receive a separate PQRS incentive payment associated with each TIN.

However, we believe that making the APM Incentive Payments to the TIN associated with the Advanced APM Entity during the QP Performance Period would be most consistent with section 1833(z) of the Act to incentivize participation in Advanced APMs. Rewarding TINs that are not involved in an Advanced APM for the activity of their constituent NPIs through separate entities seems to be antithetical to the objective of the APM Incentive Payment. We also believe that making the APM Incentive Payments to the TIN associated with the Advanced APM Entity during the QP Performance Period is most consistent with section 1833(z) of the Act with regards to making the APM Incentive Payments to eligible clinicians who become QPs. We also hope to promote simplicity and foster QP awareness of the recipient of the APM Incentive Payment that is based on their activity within APMs. We also believe that making multiple separate payments would increase complexity for both CMS and eligible clinicians.

Additionally, we proposed in section II.F.5 of this preamble, that in order to be a QP, an eligible clinician would need to be identified using a CMS maintained participation list of eligible clinicians for the Advanced APM entity. This proposal would allow CMS to track the APM Entity/TIN/NPI identifiers for each individual eligible clinician, and we believe that this information will allow CMS to determine which of the QP's TINs should receive the APM Incentive Payment.

We recognize that there may be scenarios in which an individual eligible clinician may change his or her affiliation between the QP Performance Period and the payment year such that the eligible clinician no longer practices at the TIN affiliated with the Advanced APM Entity. In this instance, we propose to make the APM Incentive Payment to the TIN provided on the eligible clinician's CMS–588 EFT Application. This proposal is consistent with the process that CMS has used to make incentive payments under other programs, such as the PCIP program.

We seek comment on our proposal to make the APM Incentive Payments to the TIN affiliated with the Advanced APM Entity through which an individual eligible clinician becomes a QP during the QP Performance Period and our proposal to make the APM Incentive Payment when an eligible clinician no longer practice at the TIN affiliated with the Advanced APM Entity. We also seek comment on alternative options that maintain the goals of equity and simplicity, and of using the APM Incentive Payment to encourage and reward participation in Advanced APMs.

(2) Exceptions

As discussed in the exceptions section II.F.5 of this preamble, we recognize that there may be instances where none of the Advanced APM Entities with which an individual eligible clinician participates meets the QP threshold. In this instance, we have proposed to assess the eligible clinician individually, using services furnished through all Advanced APM Entities during the QP Performance Period. When we make the QP determination at the individual eligible clinician level, we propose to split the APM Incentive Payment amount proportionally across all of the QP's TINs associated with Advanced APM Entities. For example, if an eligible clinician is a QP who participates in two APMs (APM 1 and APM 2), and has 75 percent of his or her payments (or patients) used to make the QP determination through APM 1 and 25 percent of his or her payments (or patients) used to make the QP determination APM 2, we would make 75 percent of the APM Incentive Payment to the TIN affiliated with APM 1, and 25 percent of the APM Incentive Payment to the TIN affiliated with APM 2. We believe that splitting the APM Incentive Payment in this way is most consistent with section 1833(z) of the Act, as well as our goal to encourage participation in APMs. We also believe that splitting the incentive payment in this way appropriately recognizes the several activities of the individual eligible clinician toward achieving the QP threshold.

CMS seeks comment on the proposal to split the APM Incentive Payment among the QP's TINs associated with Advanced APM Entities in instances where the QP determination is made at the individual eligible clinician level. We also welcome comments regarding to which TIN(s) payments should be made in the cases where the QP changes TIN affiliations between the QP Performance Period and the payments of the APM Incentive Payment.

(3) Notification of APM Incentive Payment Amount

We anticipate that the notification of the APM Incentive Payment amount will not occur at the same time as the notification of QP status, but will occur later in the year to allow for accurate calculation and validation of the incentive payment amount. We propose to send notification to both Advanced APM Entities and their individual participating QPs of their APM Incentive Payment amount as soon as CMS has calculated the amount of the APM Incentive Payment and performed all necessary validation of the results. Following our proposed method to notify eligible clinicians of their QP status, as discussed in section II.F.5 of this preamble, we propose that the APM Incentive Payment amount notification would be made directly to QPs in combination with a general public notice that such calculations have been completed for the year. For the direct QP notification, CMS intends to include the amount of APM Incentive Payment and the TIN to which the incentive payments will be made. In the case that a QP determination is made at the individual eligible clinician level, and the incentive payment is split across multiple TINS, CMS intends to identify which TINs we will make the incentive payment, and include the amount of APM Incentive Payment that will be made to each TIN. For the notification to Advanced APM Entities, CMS intends to include the total amount of APM Incentive Payments that will be made to each participating TIN within the Advanced APM Entity, as well as QP specific payment amounts. We believe that this is the most efficient method to disseminate of this information to all QPs.

We seek comment on other methods for the notification of APM Incentive Payment amount. We also seek comment on the content of such notifications so that they may be as clear and useful as possible.

9. Monitoring and Program Integrity

In an effort to accurately award the APM Incentive Payment and preserve the integrity of the Medicare program, we propose that CMS will monitor Advanced APM Entities and eligible clinicians on an ongoing basis for non-compliance with the conditions of participation for Medicare and the terms of the relevant Advanced APMs in which they participate during the QP Performance Period. This will include vetting of applicants to Advanced APMs to determine whether they are in compliance with the conditions of participation of Medicare and ongoing, periodic assessments of Advanced APM Entities and eligible clinicians by APMs in conjunction with the CMS Center for Program Integrity and other relevant federal government departments and agencies. These actions are currently taking place for APMs and will continue in the future as stated in the proposed rule.

We propose that if an Advanced APM terminates an Advanced APM Entity or eligible clinician during the QP Performance Period for program integrity reasons, or if the Advanced APM Entity or eligible clinician is out of compliance with program requirements, CMS may reduce or deny the APM Incentive Payment to such eligible clinicians. In addition, if the APM Incentive Payment is paid during the QP Performance Period and the Advanced APM Entity or eligible clinician is later terminated due to a program integrity matter arising during the QP Performance Period, CMS may recoup all or a portion of the amount of the payment from the entity to which CMS made the payment.

We also propose that CMS will reopen and recoup any payments that were made in error in accordance with procedures similar to those set forth at §§ 405.980 and 405.370 *et seq.* or established under the relevant APM.

As discussed in section II.F.7.b.(7) of the preamble, we propose that APM Entities and/or eligible clinicians must submit certain information for CMS to assess whether other payer arrangements meet the Other Payer Advanced APM criteria and to calculate the Threshold Score for a QP determination under the All-Payer Combination Option. We also propose that Advanced APM Entities and eligible clinicians must maintain copies of all records related to the All-Payer Combination Option for at least ten years and must provide the government with access to these records for auditing and inspection purposes. If an audit reveals that the information submitted is inaccurate, CMS may recoup the APM Incentive Payment. We note that nothing in this proposed rule limits or restricts the authority of the Office of the Inspector General.

We seek comment on our monitoring and program integrity proposals.

10. Physician-Focused Payment Models

a. Introduction and Overview

Section 101(e)(1) of the MACRA entitled, "Increasing the Transparency of Physician-Focused Payment Models," adds a new section 1868(c) to the Act. In general, this section establishes an innovative process for individuals and stakeholder entities (stakeholders) to propose physician-focused payment models (PFPMs) to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). A copy of the PTAC's charter, established by the Secretary on January 5, 2016, is available at ***https://aspe.hhs.gov/*** *charter-physician-focused-payment-model-technical-advisory-committee.*

(1) Overview of the Roles of the Secretary, the PTAC, and CMS

Section 1868(c)(2)(A) of the Act requires the Secretary to establish, through notice and comment rulemaking following an RFI, criteria for PFPMs (PFPM criteria), including models for specialist physicians, that could be used by the PTAC in making comments and recommendations on PFPMs. We issued the MIPS and APMs RFI requesting stakeholder input on PFPMs on October 1, 2015, and propose PFPM criteria in this rule, section II.F.10.c. of this proposed rule.

Section 1868(c)(2)(B) of the Act specifies that stakeholders may submit proposals to the PTAC on an ongoing basis for PFPMs that they believe meet the PFPM criteria established by the Secretary. We recognize this statutory directive, but do not propose to define "ongoing basis" because we believe that the process for submitting proposals to the PTAC should be determined by the PTAC.

Section 1868(c)(2)(C) of the Act requires the PTAC to review stakeholders' proposed PFPMs, prepare comments and recommendations regarding whether such PFPMS meet the PFPM criteria established by the Secretary, and submit those comments and recommendations to the Secretary.

The PTAC, established under section 1868(c)(1)(A) of the Act, is an independent committee comprised of 11 members. As required under section 1868(c)(1)(B) of the Act, the initial appointments to the PTAC were made by the Comptroller General of the United States on October 9, 2015. The terms of the first appointed members of the PTAC are intended to be staggered, with the first set of appointments for terms of 1, 2, or 3 years. After the initial appointments, all subsequent appointments would be for terms of 3 years. PTAC members who were among the initial appointments may be reappointed for subsequent 3-year terms. There are no limitations for how many terms a PTAC member may serve. No end date for the PTAC is specified. Section 1868(c)(1)(B)(ii) and (iii) of the Act state that no more than 5 members of the PTAC shall be providers of services or suppliers, or representatives of providers of services or suppliers, and no member of the PTAC shall be an employee of the federal government. We received responses to the MIPS and APMs RFI recommending that CMS ensure that the PTAC is made up of varying ratios of professionals from particular backgrounds. We appreciate these responses; however, section 1868(c) of the Act specifies that the Comptroller General of the United States is to appoint members of the PTAC. Therefore, CMS does not have the authority to appoint members of the PTAC.

Section 1868(c)(2)(D) of the Act requires the Secretary to review the PTAC's comments and recommendations on proposed PFPMs and to post "a detailed response" to those comments and recommendations on the CMS Web site. We received comments on the MIPS and APMs RFI requesting that we review PFPM proposals from stakeholders before they are submitted to the PTAC. We also received comments on the MIPS and APMs RFI requesting that the PTAC review PFPM proposals under development by stakeholders before they are formally submitted to the PTAC. Section 1868(c) of the Act does not require either the PTAC or the Secretary to evaluate proposed PFPMs prior to their submission to the PTAC, nor does it require the Secretary to review and respond to proposed PFPMs that are not reviewed by the PTAC. The PTAC would determine whether and how it may provide feedback on proposed PFPMs. In addition, we do not propose to evaluate PFPM proposals prior to their submission to the PTAC because it might interfere with the PTAC's independent review process.

We also received responses to the MIPS and APMs RFI recommending that all proposed PFPMs that the PTAC recommends to the Secretary should be tested by us. Without being able to predict the volume, quality, or appropriateness of the PFPMs that the PTAC would recommend, we are not in a position to propose a commitment to test all such models. Section 1868(c) of the Act does not require us to test models that are recommended by the PTAC and given a favorable response by the Secretary. However, this does not imply that we would not give serious consideration to proposed PFPMs recommended by the PTAC. The PTAC serves an important advisory role in the implementation of APMs, but there are additional considerations that must be made by the Secretary beyond what is provided by the PTAC, such as competing priorities and available resources. We believe that this flexibility is important because the Secretary, and CMS through its delegated authority to test APMs, must retain the ability to make final decisions on which models to test and when, based on multiple factors including those that the Innovation Center currently uses to determine which payment models to test as described in section II.F.10.d. of this proposed rule.

While we would consider these factors separately from the PTAC's review process, the decision to test a model recommended by the PTAC would not require a second application process to us as speculated by some commenters on the MIPS and APMs RFI; we would review the proposal submitted to the PTAC along with comments from the PTAC, and any other resources we believe would be useful. Proposed PFPMs that the PTAC recommends to the Secretary but that are not immediately tested by us may be considered for testing at a later time. We would continue to test PFPMs that are developed within CMS.

(2) Deadlines for the Duties of the Secretary, the PTAC, and CMS

We received multiple responses to the MIPS and APMs RFI recommending that we establish deadlines for the PTAC's comments and recommendations on proposed PFPMs, the Secretary's response to the PTAC's comments and recommendations, and our testing of PFPMs. We do not propose to set deadlines for these tasks through regulations. We believe that setting a deadline for the PTAC's comments and recommendations would interfere with the PTAC's freedom to govern itself and develop its own process and timeline for reviewing proposed PFPMs. We wish to preserve the PTAC's independence and to give it the freedom to determine how and when it would review proposed PFPMs without rulemaking.

We believe that setting a deadline through rulemaking for the Secretary's review of the PTAC's comments and recommendations, publication of a response to them, and our potential testing of a proposed PFPM submitted to the PTAC is inappropriate because these tasks would take varying amounts of time depending on factors that we cannot predict. Proposed PFPMs may be submitted to the PTAC on "an ongoing basis" in accordance with section 1868(c)(2)(B) of the Act, and given that there may be variation in the number and frequency of proposals, setting a deadline would be difficult. We do not believe we can effectively set deadlines because we do not know how many PFPM proposals the PTAC would receive. The Secretary would need varying lengths of time to review, comment on, and respond to PFPM proposals depending on the volume and nature of each proposal.

We do not believe it would be reasonable to require us to adhere to a deadline in deciding whether to test a particular proposed PFPM. It is important for us to retain the flexibility to test models when it believes that it is the right time to do so, taking into account the other models it is currently testing, any potential design changes to the proposed PFPM, interactions with other our policies, and resource allocation. APMs generally take 18 months for us to develop, although the period of development may vary in length significantly, making a deadline difficult to establish.

We received comments on the MIPS and APMs RFI suggesting that that any proposed PFPM approved by the PTAC should be available immediately for participant enrollment, and that participant enrollment should continue on an ongoing basis. We believe that setting deadlines for testing proposed PFPMs that we decide to test would be inappropriate. Entities need time to complete applications for voluntary models and we need time to review applications and prepare participation agreements for entities to sign. Entities need time to review these participation agreements and to begin planning for implementation of the model. To maintain rigorous evaluation of model outcomes, we also need time to build the necessary model infrastructure for such functions as quality measurement, financial calculations, and payment disbursements, and to coordinate with other payers if they are included in the model's design.

We believe that proposed PFPMs that meet all of the proposed criteria may need less time to go through the development process; however, we cannot guarantee that the development process would be shortened, or estimate by how much it would be shortened. These processes depend on the nature of the PFPM's design and any attempt to impose a deadline on them would not benefit stakeholders because it would not allow us to tailor its review and development process to the needs of the proposed PFPM.

b. Definition of PFPM

(1) Proposed Definition of PFPM

Section 1868(c) of the Act does not define the term "physician-focused payment model" (PFPM). In § 414.1465, we are proposing to add the following definition of PFPM: An Alternative Payment Model wherein Medicare is a payer, which includes physician group practices (PGPs) or individual physicians as APM Entities and targets the quality and costs of physician services. We propose to require a PFPM to target physician services. To address physician services, proposed PFPMs may address such elements as physician behavior or clinical decision-making. APM Entities may be individual eligible clinicians, physician group practices (PGPs), or other entities, depending on the payment model's design. Therefore a PFPM must focus on physician services and contain either individual physicians or PGPs as APM Entities, although it may also include facilities or other practitioner types.

We propose to require that PFPMs be designed to be tested as APMs with Medicare as a payer. Other Payer APMs would therefore not be PFPMs. We believe this is an appropriate standard for PFPMs because the Secretary is interested in reviewing comments and recommendations from the PTAC on models that may be tested with Medicare as a payer and because this provision is in section 1868 of the Act, and title XVIII of the Act governs Medicare. A PFPM may include other payers in addition to Medicare under the proposed definition. We believe this definition is appropriate because it would include APMs with arms of their design that would include other payers beyond Medicare, but would not include models that are only Other Payer APMs.

We received many responses to the MIPS and APMs RFI regarding the proposed definition of PFPMs. These recommendations ranged from broadening the definition to include any payment model that alters payment for particular programs or populations to restricting the definition to specialist physicians only. We also received responses to the MIPS and APMs RFI recommending the definition of PFPM be broadened to include other care providers in the definition, such as nurses. We did not accept these suggestions because we believe that a payment model that does not specifically include individual physicians or PGPs would not appropriately be termed physician-focused. While we agree that there is merit in allowing other practitioners and facilities to be included in proposed PFPMs, we do not agree that changing the definition to explicitly include additional care providers or broadening the definition such that physicians or PGPs might not be included would satisfy the statutory directives under section 1868(c) of the Act that promote the development of PFPMs. Defining PFPM to allow the inclusion of other entities and additional targets gives stakeholders more flexibility in their proposals and may lead to models that promote broader participation in PFPMs, greater potential for care redesign, and greater potential for cost reduction.

We do not propose to limit a PFPM to exclusively targeting physicians and physician services because we believe that stakeholders should be able to propose payment models that include additional types of entities, as well as additional services. We do not propose to define PFPM as a payment model that exclusively addresses Medicare FFS payments. A proposed PFPM may also include other payers in addition to Medicare, including Medicaid, Medicare Advantage, CHIP, and private payers, which may promote broader participation in PFPMs and greater potential for cost reduction. If tested as an APM, a PFPM that includes payers in addition to Medicare would include an Other Payer APM as part of its design in addition to an APM.

(2) Relationship Between PFPMs and Advanced APMs

Section 1868(c) of the Act does not require PFPMs to meet the criteria to be an Advanced APM for purposes of the incentives for participation in Advanced APMs under section 1833(z) of the Act, and we do not propose to define PFPMs solely as Advanced APMs. Stakeholders may therefore propose either Advanced APMs or other PFPMs that might lead to better care for patients, better health for our communities, and lower health care spending. We received responses to the MIPS and APMs RFI recommending that all proposed PFPMs selected for testing by us should be Advanced APMs without needing to meet the additional criteria for Advanced APMs. Section 1833(z)(3)(C) and (D) of the Act makes a clear distinction between APMs and Advanced APMs and we do not believe the statutory requirements for Advanced APMs can or should be waived for proposed PFPMs.

We recognize that both stakeholders and the PTAC may want to discuss in their proposals, comments, and recommendations, respectively, whether a proposed PFPM would be an Advanced APM. Therefore, we recommend that stakeholders provide information in their proposal about whether their proposed PFPM might be an Advanced APM as described in section II.F.4 of this proposed rule.

c. Proposed PFPM Criteria

Section 1868(c)(2)(A) of the Act requires the Secretary to establish PFPM criteria for PFPMs, including models for specialist physicians, not later than November 1, 2016. The PFPM criteria would be used by the PTAC to make comments and recommendations on proposed PFPMs to the Secretary. The proposed PFPM criteria are listed in section II.F.10.c.(1) of this rule, and at proposed § 414.1465(b). We have designed these criteria so that they are broad enough to encompass all physician specialties and provide stakeholders with flexibility in designing PFPMs.

We propose PFPM criteria organized into three categories that are consistent with the Administration's strategic goals for achieving better care, smarter spending and healthier people: Payment incentives; care delivery; and information availability. First, we propose a category of criteria that promote payment incentives for higher-value care, including paying for value over volume and providing resources and flexibility necessary for practitioners to deliver high-quality health care.

To address paying for value over volume, we propose a criterion that PFPMs should provide incentives to practitioners to deliver high-quality health care. We believe that the correct incentives are necessary to drive change to improve quality of care. To address this criterion, the PTAC may request or stakeholders may wish to provide information about specific incentives in the proposed PFPM and how they are expected to incentivize quality, or information about any adjustments to payments to APM Entities based on quality performance. Similarly, we believe that it is important for a PFPM to provide sufficient flexibility for practitioners to deliver high-quality care. Flexibility relates to operational feasibility, the PFPM's ability to adapt to accommodate clinical differences in patient subgroups, and the APM Entity's ability to respond to changes in healthcare. To address this criterion, the PTAC may request or stakeholders may wish to provide information about how feasible it would be for APM Entities in the PFPM to deliver high-quality care as defined by the PFPM, and how the model design facilitates and encourages delivery of high-value care with respect to the dynamic and evolving nature of healthcare. In addition, the PTAC may request or stakeholders may wish to provide information about how the proposed PFPM can adapt to accommodate clinical differences in patient subgroups, and how it can adapt to account for changing technology, including new drug therapies.

This category of criteria also aligns with the Innovation Center's statutory authority under section 1115A of the Act to test models aimed to improve care, reduce cost, or achieve both of these goals, by proposing a criterion that assesses to what extent a PFPM proposal is expected to achieve these goals. To address this criterion, the PTAC may request or stakeholders may wish to provide information about specific quality measures included in the PFPM's design, including any prior validation of those measures, and whether any of those measures are patient reported outcome measures or measurements of beneficiary experience of care. We believe estimates of any cost reduction under the PFPM to the most precise extent possible would also be useful in addressing this criterion.

We propose a criterion that the PFPM proposal must pay APM Entities under a payment methodology that furthers the PFPM Criteria. The payment methodology must address how it is different from current Medicare payment methodologies, and why the payment methodology cannot be tested under current payment methodologies. We believe it is necessary for PFPM proposals to contain such a payment methodology because the PTAC is tasked with reviewing payment models and therefore cannot evaluate a proposal without knowing the payment methodology. We believe that the more robust the description of the payment methodology is, the easier it would be for the PTAC to evaluate the impact of the proposed PFPM. In addition, including information about how the proposed PFPM differs from current methodologies and why it cannot be tested under them would allow the PTAC and the Secretary to evaluate how the proposed PFPM could improve on existing methodologies. It is important for the PFPM proposal to describe how the payment methodology is different from current Medicare payment methodologies to show how the PFPM would test differences in payment and their effect on paying for value over volume. It would also help the PTAC and the Secretary to understand why the PFPM would be a significant enough departure that an APM would be required to test it. We recommend that stakeholders include a thorough description of the payment methodology. To be robust, the description of a payment methodology should include the amount of any new payments to proposed APM Entities, such as per beneficiary per month payments, performance-based payments, or shared savings payments. It should also include a methodology for calculation of these payments. It should include information about whether the proposed PFPM could include other payers in addition to Medicare, and if so, the payment methodology proposed for those payers. The payment methodology description should also include information about the use of any payment methods such as bundled payments or capitated payments and a description of the type and degree of financial performance risk assumed by APM Entities. We received comments in response to the RFI suggesting that we accept proposed PFPMs that have different payment methodologies from current APMs such as ACOs and bundled payments. We welcome completely new and innovative ideas for payment methodologies that can improve care while reducing cost.

We also propose to include in the first category a criterion that the PFPM must either aim to solve an issue in payment policy not addressed in the CMS APM portfolio at the time it is proposed or include in its design APM Entities who have had limited opportunities to participate in APMs. We believe this criterion would promote participation in APMs by broadening and expanding our portfolio of APMs in areas such as geographic location, specialty, condition, and illness, without overly limiting proposed PFPMs. We believe that because proposed PFPMs may satisfy this criterion by either addressing a new issue or including a new specialty, the criterion is sufficiently broad to allow stakeholders to submit many proposed PFPMs that could expand the CMS APM portfolio. Physicians and practitioners whose opportunities to participate in other PFPMs with us have been limited to date include, for example, those who have not been able to apply for any other PFPM because one has not been designed that would include physicians and practitioners of their specialty. We propose that a proposed PFPM that includes multiple specialties may meet the PFPM criteria where a minimum of one of the specialties in the proposed PFPM is not currently being addressed by another APM. We believe this reflects the intent of section 1868(c)(2)(A)(i) of the Act which specifically directs the Secretary to establish PFPM criteria, including models for specialist physicians.

We also propose a criterion that a PFPM proposal must have evaluable goals for the impact of cost and quality under the PFPM. To make the decision to expand an APM under section 1115A(c) of the Act, the Secretary must evaluate the model's success. This standard informed our proposed criterion not only because it would be important for any APMs that are tested under section 1115A(c) of the Act, but also because it is necessary for measuring the success of any APM that it be evaluable. It is the evaluation of an APM that tells us whether the APM is successful in reducing cost or improving quality. We believe that the more detailed the information regarding how the impact of a proposed PFPM would be evaluated, the easier it would be for the PTAC to evaluate the impact of the proposed PFPM in terms of potential expansion, as well as in terms of incentivizing high quality care and reducing costs. To address this criterion, the PTAC may request or stakeholders may wish to provide information about potential approaches for evaluation including evaluation study design, comparison groups, key outcome measures, the level of precision the evaluation may reach, and the extent that the impact of each element of the PFPM can be evaluated.

Second, we propose a category of criteria that address care delivery improvements that promote better care. Here we propose criteria to address integration and care coordination, patient choice, and patient safety. To address these criteria, the PTAC may request or stakeholders may wish to provide information about how the payment model would affect access to care for Medicare beneficiaries, including an explanation of how the payment model would not reduce benefits for Medicare beneficiaries, limit coverage for beneficiaries, how the payment model would affect disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography, and what measures may be used to measure the provision of necessary care and monitor for any potential stinting of care. The PTAC may also request or stakeholders may wish to provide information about how patient choice is preserved under the model by accommodating individual differences in patient characteristics, conditions, and health-related preferences while furthering population health outcomes.

Third, we propose a category of criteria that address information enhancements that improve the availability of information to guide decision-making. We believe that information enhancements, particularly through use of technology are important to improving Medicare payment policy and delivering better care. Here we propose a criterion for encouraging use of health information technology. In addition, we recommend that stakeholders include information about any information enhancements that encourage transparency concerning cost and quality of care to patients and other stakeholders. To address these criteria, the PTAC may request or stakeholders may wish to provide information about how the payment model could increase transparency, or how the payment model could incorporate certified EHR technology.

In carrying out its review of PFPM proposals, the PTAC shall assess whether the PFPM meets the following criteria for PFPMs sought by the Secretary. The Secretary seeks PFPMs that:

(1) Incentives: Pay for higher-value care.

- Value over volume: Provide incentives to practitioners to deliver high-quality health care.
- Flexibility: Provide the flexibility needed for practitioners to deliver high-quality health care.
- Quality and Cost: Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.
- Payment methodology: Pays APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail

through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

- Scope: Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited.
- Ability to be evaluated: Have evaluable goals for quality of care, cost, and any other goals of the Physician-focused Payment Model.

(2) Care delivery improvements: Promote better care coordination, protect patient safety, and encourage patient engagement.

- Integration and Care Coordination: Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the Physician-Focused Payment Model.
- Patient Choice: Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
- Patient Safety: Aim to maintain or improve standards of patient safety.

(3) Information Enhancements: Improving the availability of information to guide decision-making.

- Health Information Technology: encourage use of health information technology to inform care.

d. Facilitating CMS Consideration of Models Recommended by the PTAC

In order to facilitate and potentially expedite the consideration of models for our testing following PTAC review and recommendation, we suggest “supplemental information elements” stakeholders may include in their PFPM proposals to assist our review. We do not propose to require these elements as PFPM criteria and defer to the PTAC on how it may approach requesting any supplemental information beyond that required to meet the PFPM criteria.

(1) Background on Factors Used To Evaluate Potential Innovation Center Models

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models. We have an established process by which it routinely assesses proposals for new models. Many factors are typically used in the selection of models to be tested, and can be viewed on the Innovation Center Web site at *https://innovation.cms.gov/Files/x/rfi-Websitepreamble.pdf*.

(2) Why and How These Factors Informed the Supplemental Information Elements for PFPM Proposals

These factors address a variety of details in an APM’s design. Examining these factors helps us to answer important questions that inform its decision whether to test a payment model. They provide necessary insight about how a potential APM would fit within our current CMS APM portfolio, including information such as the scope of its impact, likelihood of success, how many practitioners and beneficiaries it would impact, whether those potential outcomes merit the required investments and opportunity costs, and whether the impact of the payment model can be measured to determine if it should be expanded. We believe that to the extent stakeholders develop PFPM proposals that address the factors used by us in evaluating payment model designs, they would increase the probability that PTAC recommendations would be positive and might lead us to test the proposed PFPMs.

We considered each factor currently used by us when we developed the suggested supplemental information elements for PFPM submission. We balanced the burden these expectations would place on stakeholders in developing their proposed PFPMs with the value this information would provide to the PTAC in its review of the proposed PFPMs and to us in our decision whether or not to test a proposed PFPM. We acknowledge that the factors used by us may change in the future and we believe that the PFPM criteria we have proposed are sufficiently broad and relevant to our evaluation of the testing of models that they would align with any future changes in our factors. While we believe that the more detail concerning these factors the stakeholder can provide the more it would facilitate our review, we have determined that certain factors are of particular importance.

We also chose not to include certain of these factors, including the size of investment required and waiver authority, in the suggested supplemental information elements because we believe the burden to evaluate how these factors apply to potential APMs should be on us, not stakeholders. For example, we received responses to the RFI both in favor of, and opposed to requiring information about whether, if the proposed PFPM cannot be implemented under existing law, we have the authority to waive any laws or regulations for purposes of testing the payment model. We decided it would be inappropriate to require stakeholders to speculate as to the scope of our waiver authority in their proposals. We and other components of HHS are responsible for interpreting the relevant laws and regulations, and for designing and issuing any potential waivers. We also decided not to include as a supplemental information element the size of investment for proposed PFPMs because we do not believe stakeholders would have the necessary information about our operational costs to include in a PFPM proposal.

(3) Supplemental Information Elements Considered Essential to CMS Consideration of New Models

There are three pieces of information we consider fundamental to evaluating new models. First, the anticipated size and scope of a proposed PFPM is essential. For example, any proposed PFPM should describe the estimated number of Medicare beneficiaries that would be affected by the model, the number and scope of eligible clinicians expected to participate, including eligible clinician specialty(s), the potential geographic location(s) included in the model, the defined period of performance or clinical episode(s) of care in the model, and the number and quality of services that would be affected by the model. A definition of the target population and any criteria for including or excluding patients from the model would also be useful in addressing the scope of the PFPM. We believe this information is vital to evaluating a proposed PFPM. Second, we also consider an estimate of the burden in terms of morbidity and mortality on a population to be relevant in describing the scope of physician services addressed by the model. For example, stakeholders could provide estimates of morbidity and mortality from peer-reviewed publications and analyses of health care data such as Medicare or Medicaid data. Third, we believe an explanation of how a proposed model would be attractive to participate in and feasible to implement for potential APM Entities from a financial perspective is necessary for us to evaluate a proposed model.

To summarize, the following specific supplemental information elements are considered essential:

- A description of the anticipated size and scope of the model in terms of eligible clinicians, beneficiaries, and services.

- A description of the burden of disease, illness or disability on the target patient population.
- An assessment of the financial opportunity for APM Entities, including a business case for how their participation in the model could be more beneficial to them than participation in traditional fee-for-service Medicare.

In addition, we recommend that proposed PFPMs submitted to the PTAC include information about whether the stakeholder or individual submitting the proposal believes it would meet the criteria to be an Advanced APM, discussed in section II.F.4. of this proposed rule. This information would allow us to evaluate whether the proposed PFPM would provide eligible clinicians with an opportunity to become QPs for purposes of the incentives for participation in Advanced APMs. We are interested in receiving proposed PFPMs from stakeholders that would be Advanced APMs and we received comments on the RFI stating that stakeholders would like this opportunity as well. As discussed in section II.F.10.b. of this proposed rule, we do not believe that it is necessary to limit stakeholders' proposed PFPMs to only those that would be Advanced APMs, but believe that it is useful for proposed PFPMs to state whether, if tested by us, they would be Advanced APMs.

e. MIPS and APMs RFI Comments on PFPM Criteria

We received multiple responses to the MIPS and APMs RFI recommending that the Secretary include specialty-specific criteria to be used by the PTAC. We appreciate the interest from multiple specialties and encourage them to submit proposed PFPMs for review by the PTAC, but do not believe that we should limit proposed PFPMs by adding specialty-specific criteria.

We received multiple comments suggesting prioritization of certain patient groups, physician specialties, diseases, and other issues. We believe that the aim of section 1868(c) of the Act to promote development of PFPMs is best satisfied by not prioritizing certain specialties or issues over others in the PFPM criteria. However, the PTAC may decide to prioritize specific patient groups, specialties, or issues in its comments and recommendations.

We received several responses to the MIPS and APMs RFI recommending that types of physicians and practitioners that have had the opportunity to participate in previous APMs should not be excluded from future proposals for PFPMs because current or previous APMs are not exhaustive of all possible APMs for any given specialty or issue. We agree with this recommendation, so long as the proposed PFPM instead aims to solve an issue in payment policy that broadens and expands the CMS APM portfolio at the time it is tested as stated in section II.F.10.c. of this proposed rule. We believe this best serves our goal of expanding and diversifying our portfolio of APMs. We believe that concurrently implementing multiple PFPMs that attempt to solve the same clinical or payment issue may not be the most efficient use of limited resources, and may complicate the evaluations of some or all of the relevant models. However, we would consider a proposed PFPM that focuses on an issue addressed in a model that we are no longer testing, even if that prior model was unsuccessful.

We also received responses to the MIPS and APMs RFI recommending that we should consider proposals that modify or extend the testing of existing models. We do not believe that the PTAC is the proper forum for considering modifications or extensions of current models. We also note that our legal authority to modify or extend existing models is contingent on other criteria that are unrelated to the criteria for proposed PFPMs. Stakeholders who wish to discuss changes to models that we are currently testing may discuss them with us directly, outside of the PTAC review process.

We received many comments suggesting payment for high-value services that we do not currently (or separately) reimburse as examples of potential PFPMs. These types of changes are an important part of moving toward value-based delivery system reform, but adding payment for specific services without any other change does not constitute a sufficient departure from current payment methodologies to meet our proposed PFPM criteria or to be considered an APM, and could be better achieved outside of the PTAC process. We do however welcome these suggestions within the context of broader model proposals.

We received responses to the MIPS and APMs RFI recommending that in addition to criteria about how the proposed PFPM would either fit in to or replace the existing Medicare payment system, there should also be criteria to identify specific barriers to care improvement that exist in the current payment system. We believe that information about how the proposed PFPM changes or fits into existing payment systems is essential to understanding how the proposed PFPM operates. We believe information about existing barriers to improving care and reducing costs and how the proposed PFPM addresses those barriers is also important. Therefore, we encourage stakeholders to include this information in their proposals although we do not propose to require it.

We received many responses to the MIPS and APMs RFI recommending that the PFPM criteria include specific quality measures and guidelines, such as those set by the Core Quality Measures Collaborative. We do not believe it would be appropriate to limit proposed PFPMs to include specific quality measures. We encourage stakeholders to propose quality measures that are tailored to their particular proposed PFPM. We also received responses to the MIPS and APMs RFI recommending we should not include criteria requiring information on the impact that the proposed PFPM would have on quality of care. We understand that the full scope of the potential impact a proposed PFPM may have on quality of care and cost reduction might not be known at the time of submission. However, we believe proposed PFPMs should provide realistic assessments and estimates of the impacts, as well as information to justify these estimates. Commentators also voiced opinions about the utilization of Clinical Data Registries managed by specialty societies or other groups. We believe that this information, if applicable, should be included in the PFPM proposal as an aspect of CEHRT use.

Finally, we received many responses to the MIPS and APMs RFI offering proposed PFPMs that we should implement. We appreciate the interest in PFPMs and encourage these commenters to submit their proposed PFPMs to the PTAC.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Wage Estimates

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates and the December 2015 Employer Costs for Employee Compensation. In this regard, Table 46 presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wages for Billing and Posting Clerks, Computer Systems Analysts, and Physicians. We are adjusting our employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of time spent by employees of regulated entities. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods. In addition, in order to calculate the costs to beneficiaries for their time, we have used Bureau of Labor Statistics (BLS) estimates for Civilian, all occupations. We have not adjusted these costs for fringe benefits and overhead because only the direct wage costs represent the "opportunity cost" to beneficiaries themselves for time spent in health care settings.

TABLE 46: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Billing and Posting Clerks	43-3021	17.10[i]	17.10	34.20
Computer Systems Analysts	15-1121	41.98[i]	41.98	83.96
Physicians	29-060	91.23[i]	91.23	182.46
Civilian, All Occupations	Not applicable	23.06[ii]	N/A	23.06

[i] Source: "Occupational Employment and Wage Estimates May 2014," U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm.

[ii] Source: "December 2015 Employer Costs for Employee Compensation". U.S. Department of Labor, Bureau of Labor Statistics, http://www.bls.gov/news.release/archives/ecec_03102016.htm.

B. A Framework for Understanding the Burden of MIPS Data Submission

Because the entities permitted to submit MIPS data on behalf of eligible clinicians will vary based on APM participation and the type of data, Table 47 presents a framework for understanding the entities facing the burden of MIPS data submission. As shown in the first row of Table 47, eligible clinicians that are not in APMs will submit data either as individuals or groups to the quality, advancing care information, and CPIA performance categories.[19]

For APMs, the entities submitting data on behalf of model participants will vary across categories of data and APM Model. When APM Entities submit quality data to fulfill the requirements of their APMs, the burden will be ascribed to their APMs, and will not contribute to the MIPS data submission burden.[20] Many APM participants will be scored on advancing care information and CPIA performance categories, and the submitting entity for those categories differs between the Shared Savings Program and other APMs. For the Shared Savings Program, billing TINs (or groups) will submit advancing care information and CPIA performance category data on behalf of model participants.[21] In other APMs, eligible clinicians will submit data as individuals to the advancing care information and CPIA performance categories. For Advanced APMs, Partial Qualifying APM Participant (Partial QP) elections (which will be discussed in more detail in Section I below) will be submitted by the Advanced APM Entity on behalf of all its participating eligible clinicians.

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[19] Eligible clinicians will not be required to submit data for the resource use performance category. Resource use measures will be calculated using administrative claims data.

[20] The quality data that APM participants or Entities submit to fulfill the requirements of their models are not subject to the requirements of the Paperwork Reduction Act. Sections 3021 and 3022 of the Affordable Care Act exempt any collection of the information shared with the Shared Savings Program or Innovation Center APMs with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

TABLE 47: Entities Submitting MIPS Data On Behalf of Clinicians, by Type of Data and Category of Clinician

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Advancing Care Information Performance Category**	**CPIA Category**	**Partial QP Election**
Eligible Clinicians (not in APMs)	As groups or individuals	As groups or individuals.	As groups or individuals.	Not applicable
Eligible Clinicians participating in the Shared Savings Program	Shared Savings Program participants report at the ACO level.	Shared Savings Program participants will report at Billing TIN level.	Shared Savings Program participants will report at Billing TIN level.	For Tracks determined to be Advanced APMs, Advanced APM Entities will make election for participating eligible clinicians.
Eligible Clinicians in the Next Generation ACO Model	Next Generation ACO Model participants report at the ACO level.	Next Generation ACO Model participants will report as individuals.	Next Generation ACO Model participants will report as individuals.	If the Next Generation ACO Model is determined to be an Advanced APM, Advanced APM Entities will make election for participating eligible clinicians.
Eligible Clinicians participating in APMs (other than the Shared Savings Program or Next Generation ACO Model)	Not applicable in MIPS Year 1	APM participants in APMs other than Shared Savings Program will report as individuals.	APM participants in APMs other than Shared Savings Program will report as individuals.	For Advanced APMs, Advanced APM Entities will make election for participating eligible clinicians.

C. ICRs Regarding Quality Performance Reporting Category (§ 414.1330 and § 414.1335 and Section II.E.5.b of This Preamble) and Previously Approved Under PQRS

This section discusses the information collection requirements for the eligible clinicians who are not APM participants because burden for APM Entities' submission of quality data to fulfill the requirements of their APMs will not be ascribed to MIPS.[22] Based on historical data in the 2014 PQRS Experience Report, we estimate that up to 703,467 MIPS eligible clinicians will submit quality performance category data including those participating as groups. Because of the exclusion of QPs from our quality performance data burden estimates, our estimates of the number of eligible clinicians submitting MIPS quality data is lower than the estimate of 822,810 professionals that submitted quality data to the 2014 PQRS.[23] We assume that clinicians not in APMs that reported quality data to PQRS in 2014 will continue to report quality data to MIPS. We assume that some of those clinicians will be submitting voluntarily because they are not required (but are allowed) to report quality data to MIPS because they are in specialties not required to participate in MIPS.

We assume that the number of MIPS eligible clinicians who will submit through claims mechanisms (299,169), Qualified Registry or QCDR-mechanisms (214,590), certified EHR technology mechanisms (77,241), and as groups through CMS Web Interface (112,467) will be the same as the numbers submitting data through those mechanisms under the 2014 PQRS.[24]

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[22] For example, this burden estimate does not include CMS Web Interface or CAHPS data that will be submitted by Shared Savings Program and NextGen ACO Entities to fulfill the requirements of their models.

[23] *See https://www.cms.gov/site-search/search-results.html?q=PQRS%20Experience%20Report.* Our estimate of 703,467 eligible clinicians that will submit quality performance category data as individuals or groups is the sum of the eligible clinicians submitting data in each of the different submission mechanisms. (703,467 = 299,169 + 214,590 + 77,241 + 112,467).

[24] The most recently available counts of eligible clinicians submitting to PQRS are from 2014.

We also assume that the number of groups that will submit quality performance category data through the CMS Web Interface will be the same as the number submitting PQRS data through the GRPO Web Interface in 2014 (300 groups submitting on behalf of 112,467 MIPS eligible clinicians). Historically, the PQRS has never experienced 100 percent participation; the participation rate for 2014 was 63 percent.

For MIPS eligible clinicians or groups, the burden associated with the requirements of the MIPS quality performance category is the time and effort associated with MIPS eligible clinicians identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to submit the MIPS eligible clinician's measures. We believe it is difficult to quantify the burden accurately because MIPS eligible clinicians and groups may have different processes for integrating quality reporting into their practices' work flows. Moreover, the time needed for an MIPS eligible clinician to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary, along with the number of measures that are potentially applicable to a given professional's practice.

For MIPS eligible clinicians and groups, we estimate a total of 6 hours as the amount of time needed for an MIPS eligible clinician's billing clerk to review the quality measures list, review the various submission options, select the most appropriate submission option, identify the applicable measures or specialty measure sets for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate submission of the selected measures or specialty measure sets into the office work flows. The measures list contains the measure title and brief summary information for the MIPS eligible clinician's billing clerk to review. The 6 hour estimate for the billing clerk is comprised of reviewing the performance criteria (up to 2 hours) and reviewing measure specifications (up to 4 hours). Assuming the MIPS eligible clinician has received no training from his/her specialty society, we estimate it will take an MIPS eligible clinician's billing clerk up to 2 hours to review this list, review the submission method, and select a submission method and measures on which to report. If an MIPS eligible clinician has received training, then we believe this would take less time. We believe 4 hours is a reasonable estimate for an MIPS eligible clinician's billing clerk to review the measure specifications of measures they select to report and to develop a mechanism for incorporating submission of the selected measures or into the office work flows. Further, we estimate that it will take a physician up to 1 hour to review MIPS quality performance category measure specifications for each MIPS eligible clinician.[25] Therefore, we believe that the start-up cost for a MIPS eligible clinician's billing clerk to report measures data may be calculated as: 6 hours × $34.20/hour = $205.20, and the start-up cost for a physician to review quality performance category measure specifications to be calculated as 1 hour × $182.46/hour = $182.46.[26] These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate table.[27]

We believe the burden associated with actually submitting the quality measures will vary depending on the submission method selected by the MIPS eligible clinician. As such, we break down the burden estimates by MIPS eligible clinicians and groups according to the submission method used. The revised quality performance requirements and burden estimates will be submitted along with all other ICRs listed below under a new OMB control number (0938–NEW).

1. Burden for Quality Performance Category Reporting by MIPS Eligible Clinicians: Claims-Based Submission

We anticipate the claims submission process for MIPS will be operationally similar as it was under the PQRS. MIPS eligible clinicians must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. MIPS eligible clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–0999. This rule does not revise either of those forms. We note that the claims submission option is only available to individual MIPS eligible clinicians and is not available for groups.

The total estimated burden will vary along with the volume of claims on which the quality data is reported. Based on our experience with the PQRS, we estimate that the burden for submission of quality data will range from 7.22 hours to 17.8 hours per MIPS eligible clinician. The wide range of estimates for the time required for a MIPS eligible clinician to submit quality measures via claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 48 we also estimate that the cost of quality data submission will range from $18.47 (.22 hours × $83.96) to $906.77 (10.8 hours × $83.96). The total estimated annual cost per MIPS eligible clinician ranges from the minimum burden estimate of $406.13 to a maximum burden estimate of $1,294.43. The burden will involve becoming familiar with MIPS data submission requirements. Therefore, we believe that the start-up cost for a MIPS eligible clinician's billing clerk to report measures data may be calculated as: 6 hours × $34.20/hour = $205.20, and the start-up cost for a physician to review quality performance category measure specifications to be calculated as 1 hour × $182.46/hour = $182.46. Therefore, total annual burden cost is estimated to range from a minimum burden estimate of $121,501,865 (299,169 × $406.13) to a maximum burden estimate of $387,252,730 (299,169 × $1294.43).

Based on the assumptions discussed above, Table 48 summarizes the range of total annual burden associated with MIPS eligible clinicians using the claims submission mechanism.

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[25] Lawrence P. Casalino *et al*, "US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures," *Health Affairs*, 35, no. 3 (2016): 401–406.

[26] Because MIPS has different reporting requirements than PQRS, the assumptions for the burden of startup costs of reporting are higher than they were under the most recently approved PQRS PRA package (OMB Control Number (OCN) 0938–105). The PQRS burden estimate was based on the assumption that startup costs involved five hours at a clerk's labor rate, and 0 hours of a physician's time.

[27] The one exception is the start-up cost for a billing clerk to submit data is not listed in the CMS Web Interface Reporting Burden.

[28] In Tables 47–56, the numbers have been truncated to two decimals for readability.

TABLE 48: Burden Estimate for Quality Performance Category: MIPS Eligible Clinicians Using the Claims Submission Mechanism[28]

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
Estimated # of Participating MIPS Eligible Clinicians (a)	299,169	299,169	299,169
Burden Hours Per MIPS Eligible Clinician to Report Quality Data (b)	0.22	1.58	10.80
Estimated # of Hours Per MIPS Eligible Clinician to Prepare for MIPS Participation (c)	6	6	6
Estimated # of Hours Per Physician to Review Measure Specifications (d)	1	1	1
Estimated Annual Burden hours per provider (e) = (b) + (c) + (d)	**7.22**	**8.58**	**17.8**
Estimated Total Annual Burden Hours (f) = (a)*(e)	**2,160,000**	**2,566,870**	**5,325,208**
Estimated Cost Per MIPS Eligible Clinician to Report Quality Data (@ computer systems analyst's labor rate of $83.96/hr.) (g)	$18.47	$132.66	$906.77
Estimated Cost Per Eligible Clinician to Prepare for MIPS Participation (@ clerk's labor rate of $34.20/hr.) (h)	$205.20	$205.20	$205.20
Estimated Cost Per Eligible Clinician to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (i)	$182.46	$182.46	$182.46
Estimated Total Annual Cost Per Eligible Clinician (j) = (g)+(h)+(i)	$406.13	$520.32	$1,294.43
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$121,501,865**	**$155,662,657**	**$387,252,730**

2. Burden for Quality Performance Category Reporting by MIPS Eligible Clinicians and Groups Using Qualified Registry and QCDR Submissions

For qualified registry and QCDR submissions, we estimate an additional time burden for MIPS eligible clinicians and groups to become familiar with MIPS submission requirements and, in some cases, new specialty measure sets. Therefore, we believe that the start-up cost for a MIPS eligible clinician's billing clerk to report measures data may be calculated as: 6 hours × $34.20/hour = $205.20, and the start-up cost for a physician to review quality performance category measure specifications to be calculated as 1 hour × $182.46/hour = $182.46. These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate table.

Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in MIPS. However, MIPS eligible clinicians and groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes (0.083 hours) per MIPs eligible clinician for a total burden cost of $6.97, at a computer systems analyst's labor rate. Hence, we estimated 10.083 burden hours per MIPS eligible clinician, with annual total burden hours of 2,163,711 (10.083 burden hours × 214,590 MIPS eligible clinicians). The total estimated annual cost per MIPS eligible clinician is estimated to be approximately $646.51. Therefore, total annual burden cost is estimated to be $138,734,298 (214,590 × $646.51). Based on these burden requirements and the number of eligible clinicians historically using the Qualified Registry and QCDR submissions, we have calculated a burden estimate for quality performance category reporting for these submissions:

TABLE 49: Burden Estimate for Quality Performance Category: MIPS Eligible Clinicians (Participating Individually or as Part of a Group) Using the Qualified Registry/QCDR Submission

	Burden Estimate
Estimated # of Participating Eligible Clinicians (a)	214,590
Estimated Burden Hours Per MIPS Eligible Clinician to Report Quality Data (b)	3
Estimated # of Hours Per MIPS Eligible Clinician to Prepare for MIPS Participation (c)	6
Estimated # of Hours Per Physician to Review Measure Specifications (d)	1
Estimated # of Hours Per MIPS Eligible Clinician to Authorize Qualified to Report on Eligible Clinician's Behalf) (e)	0.083
Estimated Annual Burden hours per provider (f) = (b) + (c) + (d) +(e)	10.083
Estimated Total Annual Burden Hours (g) = (a)*(f)	**2,163,711**
Estimated Cost Per Eligible Clinician to Report Quality Data (@ computer systems analyst's labor rate of $83.96/hr.) (h)	$251.88
Estimated Cost Per Eligible Clinician to Prepare for MIPS Participation (@ clerk's labor rate of $34.20/hr.) (i)	$205.20
Estimated Cost Per MIPS Eligible Clinician to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (j)	$182.46
Estimated Burden for Submission Tool Registration etc. (@ computer systems analyst's labor rate of $83.96/hr.) (k)	$6.97
Estimated Total Annual Cost Per Eligible Clinician (l) = (h)+(i)+(j)+(k)	$646.51
Estimated Total Annual Burden Cost (m) = (a)*(l)	**$138,734,298**

3. Burden for Quality Performance Category Reporting by Eligible Clinician and Groups: EHR Submission

Based on our experience with the PQRS, we estimate that the time needed to perform all the steps necessary for MIPS eligible clinicians to report quality performance measures includes the time to prepare for participating in quality performance category submissions for MIPS (calculated at 6 hours plus 1 hour of physician time for reviewing specifications), and an additional 3 hours for data submission through an EHR.

For EHR submission, the MIPS eligible clinician or group must review the quality measures on which we will be accepting MIPS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. To submit data to CMS directly from their EHRs, MIPS eligible clinicians must have access to a CMS-specified identity management system which we believe takes less than 1 hour to obtain. Once an MIPS eligible clinician has an account for this CMS-specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. We estimate that obtaining a CMS-specified identity management system will require 1 hour per MIPS eligible clinician cost of $83.96 (1 × $83.96), and that submitting a test data file to CMS will also require 1 hour for a per MIPS eligible clinician for a cost of $83.96. With respect to submitting the actual data file for the respective reporting period, we believe that this will take an MIPS eligible clinician or group no more than 2 hours for a per MIPS eligible clinician cost of submission of $167.92 (2 × $83.96). The burden will involve becoming familiar with MIPS submission. In addition, we believe that the start-up cost for a MIPS eligible clinician's billing clerk to report measures data may be calculated as: 6 hours × $34.20/hour = $205.20, and the start-up cost for a physician to review quality performance category measure specifications to be calculated as 1 hour × $182.46/hour = $182.46. Hence, we estimated 11 burden hours per MIPS eligible clinician, with annual total burden hours of 849,651 (11 burden hours × 77,241 MIPS eligible clinicians). The total estimated annual cost per MIPS eligible clinician is estimated to be $723.50. Therefore, total annual burden cost is estimated to be $55,883,864 (77,241 × $723.50).

Based on these burden requirements and the number of eligible clinicians historically using the EHR submission mechanism, we have calculated a burden estimate for quality performance category reporting for this submission mechanism:

TABLE 50: Burden Estimate for Quality Performance Category MIPS Eligible Clinicians (Reporting Individually or as Part of a Group) Using the EHR Submission Mechanism

	Burden Estimate
Estimated # of Participating Eligible Clinicians (a)	77,241
Estimated Burden Hours Per MIPS Eligible Clinicians to Obtain Account in CMS-Specified Identity Management System (b)	1
Estimated Burden Hours Per MIPS Eligible Clinicians to Submit Test Data File to CMS (c)	1
Estimated Burden Hours Per MIPS Eligible Clinicians to Submit MIPS Quality Data File to CMS (d)	2
Estimated # of Hours Per MIPS Eligible Clinicians to Prepare for MIPS Participation (e)	6
Estimated # of Hours Per Physician to Review Measure Specifications (f)	1
Estimated Annual Burden hours per MIPS Eligible Clinicians (g) = (b) + (c) + (d) +(e)+(f)	11
Estimated Total Annual Burden Hours (h) = (a)*(g)	**849,651**
Estimated Cost Per MIPS Eligible Clinicians to Obtain Account in CMS-specified identity management system (@ computer systems analyst's labor rate of $83.96/hr.) (i)	$83.96
Estimated Cost Per MIPS Eligible Clinicians to Submit Test Data File to CMS (@ computer systems analyst's labor rate of $83.96/hr.) (j)	$83.96
Estimated Cost Per MIPS Eligible Clinicians to Report Quality Data (@ computer systems analyst's labor rate of $83.96/hr.) (k)	$167.92
Estimated Cost Per Eligible Clinicians to Prepare for MIPS Participation (@ clerk's labor rate of $34.20/hr.) (l)	$205.20
Estimated Cost Per MIPS Eligible Clinicians to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (l)	$182.46
Estimated Total Annual Cost Per MIPS Eligible Clinicians (m) = (i)+(j)+(k)+(l)	**$723.50**
Estimated Total Annual Burden Cost (m) = (a)*(l)	**$55,883,864**

4. Burden for Quality Performance Category Reporting for Groups Using the CMS Web Interface

We estimate that 112,467 MIPS eligible clinicians submitting as 300 groups will participate in MIPS using the CMS Web Interface in the 2017 Performance Period. Groups interested in participating in the MIPS using the CMS Web Interface must complete a registration process. However, since a group using the CMS Web Interface would not need to determine which measures to report under MIPS, we believe that the registration process is handled by the group's administrative staff. We estimate that the registration process for groups under MIPS involves approximately 1 hour per group. We assume that the group staff involved in the group registration process has an average labor cost of $34.20 per hour. Therefore, assuming the total burden hours per group associated with the group registration process is 1 hour, we estimate the total cost to a group associated with the group registration process to be approximately $34.20 ($34.20 per hour × 1 hour per group).

The burden associated with the group submission requirements under the CMS Web Interface is the time and effort associated with the group submitting the quality measures data. For physician groups, this would be the time associated with the physician group completing the CMS Web Interface. We estimate that, on average, it will take each group 79 hours to submit quality measures data via the CMS Web Interface at a cost of $83.96 per hour, for a total cost of $6,6632.84 (79 × $83.96). We also estimate that a physician for each group will need to spend 1 hour per year to review quality performance measure specifications, for a total cost of $182.46. As mentioned above, we estimate it will take 1 hour for a group to register to submit through the CMS Web Interface, for a total of cost of $34.20 (1 × $34.20). Therefore, the total estimated annual cost per group is estimated to be approximately $6,632.84. The total annual burden hours are estimated to be 24,300 (300 eligible groups × 81 annual hours), and the total annual burden cost is estimated to be $2,052,850 (300 × $6,849.50).

Based on the assumptions discussed above we have calculated the following burden estimate for groups submitting to MIPS with the CMS Web Interface.

TABLE 51: Burden Estimate for Quality Performance Category Group Submission via the CMS Web Interface

	Burden Estimate
Estimated # of Eligible Group Practices (a)	300
Estimated # of Burden Hours Per Group to Register for CMS Web Interface (b)	1
Estimated # of Burden Hours Per Group to Review Measure Specifications (c)	1
Estimated # of Burden Hours Per Group to Submit (d)	79
Estimated Total Annual Burden Hours Per Group (e) = (b)+(c)+(d)	81
Estimated Total Annual Burden Hours (f) = (a)*(e)	**24,300**
Estimated Cost Per Group to Register to Participate in MIPS Under the Group Submission Option (@ clerk's labor rate of $34.20/hr.) (g)	$205.20
Estimated Cost Per Group to Submit (@ computer systems analyst's labor rate of $83.96/hr.) (h)	$6,632.84
Estimated Cost Per Group to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (i)	$182.46
Estimated Total Annual Cost Per Group (j) = (g)+(h)+(i)	$76,849.50
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$ 2,054,850**
	By Provider
Estimated # of Participating Eligible Clinicians (l)	112,467
Average Burden Hours Per Eligible Clinician (m) = (f) ÷ (l)	0.23
Estimated Cost Per Eligible Clinician to Submit Quality Data (n) = (k) ÷ (l)	$18.27

D. ICRs Regarding Burden for Third Party Reporting and Data Validation (§ 414.1400 and § 414.1390)

1. Burden for Qualified Registry and QCDR Self-Nomination[29]

For CY 2015, 98 qualified registries and 49 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS.[30] Under MIPS we believe that the number of QCDRs and qualified registries will increase because (1) many MIPS eligible clinicians will be able to use the qualified registry and QCDR for all MIPS submission (not just for quality submission) and (2) QCDRs will be able to provide innovative measures that address practice needs. Qualified registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf will need to complete a self-nomination process in order to be considered qualified to submit on behalf of MIPS eligible clinicians or groups, unless the qualified registry or QCDR was qualified to submit on behalf of MIPS eligible clinicians or groups for prior program years and did so successfully. We estimate that the self-nomination process for qualifying additional qualified registries or QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 1 hour per qualified registry or QCDR to complete the online self-nomination process.

Please note that the self-nomination statement is an online form that entities will use to provide information on their business. The self-nomination statement will be available at *https://jira.oncprojectracking.org/login.jsp.*[31]

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as meet with CMS officials when additional information is needed. In addition, QCDRs must benchmark and calculate their measure results. We note, however, that many of these capabilities may already be performed by QCDRs for purposes other than to submit data to CMS for MIPS. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a qualified registry or QCDR will spend an additional 9 hours performing various other functions related to being a MIPS qualified registry or QCDR.

We estimate that the staff involved in the qualified registry or QCDR self-nomination process will mainly be Computer Systems Analysts or the equivalent, at an average labor cost of $83.96/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, the annual burden hours is 1,500 (150 QCDRs × 10 hours). We estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately $839.60 ($83.96 per hour × 10 hours per qualified registry). We also estimate that 150 new qualified registries or QCDRs will go through the self-nomination process leading to a total burden of $125,940 ($839.60 × 150).

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[29] We do not anticipate any changes in the CEHRT process for health IT vendors as we transition to MIPS. Hence, health IT vendors are not included in the burden estimates for MIPS.

[30] The full list of qualified registries for 2015 is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015QualifiedRegistries.pdf* and the full list of QCDRs is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015QCDRPosting.pdf.*

[31] The current online self nomination form for QCDRs and qualified registries was approved under the PQRS PRA (OMB Control Number (OCN) 0938–105). We anticipate the MIPS form will be very similar to the PQRS online form.

The burden associated with the qualified registry and QCDR submission requirements in MIPS will be the time and effort associated with the qualified registry calculating quality measures results from the data submitted to the qualified registry or QCDR by its participants and submitting the quality measures results, the numerator and denominator data on quality measures, and the advancing care information performance category and CPIA data to CMS on behalf of their participants. We expect that the time needed for a qualified registry or QCDR to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures and the advancing care information performance category and CPIA data on their participants' behalf will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry or QCDR and the number of applicable measures. However, we believe that qualified registries and QCDRs already perform many of these activities for their participants. Therefore, there may not necessarily be an additional burden on a particular qualified registry or QCDR associated with calculating the measure results and submitting the measures results and numerator and denominator data on the quality measures to CMS on behalf of their MIPS participants. Whether there is any additional burden to the qualified registry or QCDR as a result of the qualified registry's or QCDR's participation in MIPS will depend on the number of measures that the qualified registry or QCDR intends to report to CMS and how similar the qualified registry's measures are to CMS' MIPS quality measures.

Based on the assumptions previously discussed, we provide an estimate of total annual burden hours and total annual cost burden associated with a qualified registry or QCDR self-nominating to be considered "qualified" for the purpose of submitting quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 52: Burden Estimate for QCDR and Registry Self Nomination

	Burden Estimate
Estimated # of Qualified registries or QCDRs Self-Nominating for the PQRS (a)	150
Estimated Total Annual Burden Hours Per Qualified registry or QCDR (b)	10
Estimated Total Annual Burden Hours For Qualified registries or QCDRs (c) = (a)*(b)	**1,500**
Estimated Cost Per Qualified registry or QCDR (d) (@ computer systems analyst's labor rate of R83.96/hr.)	$839.60
Estimated Total Annual Burden Cost For Qualified registries or QCDRs (e) = (a)*(d)	**$125,940**

2. Burden for MIPS Data Validation

Under MIPS, a CMS contractor will conduct a data validation survey in order to identify and address problems with data handling, data accuracy, and incorrect payments for the MIPS Program. Because the data that will be submitted by, or on behalf of, MIPS eligible clinicians to the MIPS Program will be used to calculate payment adjustments, it is critical that this data be accurate. Additionally, the data will be used to generate Feedback Reports for MIPS eligible clinicians and groups and, in some cases, is posted publicly on the CMS Web site, further supporting the need for accurate and complete data. The CMS data validation contractor will conduct surveys of Groups, Registries, Qualified Clinical Data Registries (QCDRs), EHR Vendors, and MIPS eligible clinicians in support of evaluating the data submitted for MIPS. The MIPS Data Validation survey will be similar to the PQRS Data Validation Survey. The PQRS Data Validation Survey uses a series of approximately thirty questions, arranged by category, to gather information about data handling practices, training, and quality assurance, as well as the challenges that stakeholders faced in participating in the PQRS program. Under MIPS, the survey's topics will be expanded beyond validation of quality measures to include CPIA and potentially advancing care information performance category data.

The MIPS Data Validation Survey for Performance Year 2017 will be conducted in late 2018 for data reported in early 2018. Because the MIPS verification process is still under development, the precise sample size for respondents has not yet been determined. We anticipate that at most 500 entities would be contacted for MIPS data verification for Performance Year 2017. Based on the most recent year of the PQRS data validation survey, we will assume that the response rate will be 86 percent. Hence, we estimated the total number of respondents for Performance Year 1 will be 430 (500 entities contacted × 86 percent response rate).

We estimate the total annual burden for the ongoing MIPS data validation will be up to 750 hours each performance year (500 responses × 1.5 hours), and the data validation will be conducted at a clerk's labor rate of $34.20 per hour for a total burden cost of $25,650 ($34.20 × 1.5).

TABLE 53: Total Estimated Burden for MIPS Data Validation

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
430	430	1.5	645	$34.20	$22,059

E. Burden for Reporting Quality Performance Category via CAHPS for MIPS Survey

Under MIPS, groups may elect to report on the CAHPS for MIPS Survey by contracting for survey administration with a CMS approved vendor. At this point, we do not believe that the groups that elect to report on CAHPS for MIPS will experience additional burden because CAHPS will cover one of their six Quality performance category measures. Beneficiaries will experience burden under the CAHPS survey; and because the survey will be similar to the CAHPS for PQRS survey, we are assuming that the burden per beneficiary will be the same.[32]

The usual practice in estimating the burden on public respondents to surveys such as CAHPS is to assume that respondent time is valued, on average, at civilian wage rates. As previously explained, the BLS data show the average hourly wage for civilians in all occupations to be $23.06. Although most Medicare beneficiaries are retired, we believe that their time value is unlikely to depart significantly from prior earnings expense, and have used the average hourly wage to compute the dollar cost estimate for these burden hours.

Under the first performance year of MIPS, we assume the number of groups that elect to report on the CAHPS for MIPS survey will be the same as 2014, when the CAHPS for PQRS survey was used. Table 54 shows the estimated annualized burden for beneficiaries to participate in the CAHPS for MIPS survey. We assume that all 300 groups submitting via the CMS Web Interface will elect to use the CAHPS for MIPS Survey. Based on historical information on the numbers of CAHPS for PQRS respondents, we assume that an average of 287 beneficiaries will respond per group. The CAHPS Survey for MIPS will be administered to approximately 86,100 beneficiaries per year (300 groups × an average of 287 beneficiaries per group responding). The survey contains 83 items and is estimated to require an average administration time of 18.4 minutes in English (at a pace of 4.5 items per minute) and 22 minutes in Spanish (assuming 20 percent more words in the Spanish translation), for an average response time of 20.24 minutes or 0.337 hours. These burden and pace estimates are based on CMS's experience with surveys of similar length that were fielded with Medicare beneficiaries. As indicated below, the annual total burden hours are estimated to be 29,106 hours (86,100 respondents × .337 burden hours per respondent to report).

TABLE 54: Burden Estimate for Beneficiary Participation in CAHPS for MIPS Survey

	Burden Estimate
Estimated # of Eligible Groups Administering CAHPS for Physician Quality Reporting Survey (a)	300
Estimated # of Beneficiaries Per Group Responding to Survey (b)	287
Estimated # of Total Respondents Reporting (c)=(a)*(b)	86,100
Estimated # of Burden Hours Per Respondent to Report (d)	0.337
Estimated Cost Per Beneficiary Reporting (at cost rate of $23.06) (e)	$7.77
Estimated Total Annual Burden Hours (f) = (c)*(d)	**29, 106**
Estimated Total Annual Burden Cost for Beneficiaries Responding to CAHPS for MIPS (g)=(a)*(e)	$669,102

F. ICRs Regarding Burden Estimate for Advancing Care Information Performance Category (§ 414.1375 and Section II.E.5.g. of This Preamble)

Advancing care information performance category data will not be submitted separately by MIPS eligible clinicians in most cases as was required under the Medicare EHR Incentive Program. MIPS eligible clinicians and clinician groups will submit this data using the same submission mechanism, or a similar submission mechanism they have selected for the other MIPS performance categories. For the purpose of submission advancing care information performance category objectives and measures under the MIPS, we have proposed in section II.E.1.f. of this proposed rule to allow for MIPS eligible clinicians to submit advancing care information performance category data through qualified registry, EHR, QCDR, and CMS Web Interface submission methods. Also, we have streamlined the submission requirements for advancing care information as part of the MIPS program. Compared to the reporting requirements in the 2015 Medicare EHR Incentive Program Final Rule, two objectives and their associated measures (Clinical Decision Support and

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[32] We are not proposing any changes to the CMS survey vendor certification process as we transition from CAHPS for PQRS to CAHPS for MIPS. Hence, we do not anticipate any new reporting burden for CAHPS survey vendors.

Computerized Provider Order Entry) will no longer be required for submission purposes. We have also worked to align the advancing care information performance category with other MIPS performance categories, such as submitting eCQMs to the quality category, which will streamline submission requirements and reduce MIPS eligible clinician confusion. Hence, a MIPS eligible clinician's estimated burden for the advancing care information performance category is lower than the estimated 7 hours per MIPS eligible clinician in the Medicare EHR Incentive Program—Stage 3 PRA (OMB control number 0938–1278) currently under review at OMB. We are requesting that effective January 1, 2017, the MIPS Collection of Information Requirements replace those for eligible clinicians in the Medicare EHR Incentive Program Stage 3 PRA.[33]

As noted above in Section B, a variety of entities will report advancing care information performance category data on behalf of clinicians. Based on historical data and 2015 Medicare EHR Incentive Program attestation, we estimate that approximately 436,500 clinicians not participating in APMs would submit advancing care information performance category data to MIPS.

TABLE 55: Estimated Numbers of Entities Submitting Advancing Care Information Performance Category Data on Behalf of Clinicians

Category of Clinician	Available Mechanisms for Submission	Estimated Number of Entities Submitting Data
Eligible Clinicians (not in APMs)	As groups or individuals.	436,500 eligible clinicians submitting as individuals
Eligible Clinicians participating in the Shared Savings Program Tracks 1, 2, and 3	Shared Savings Program participants will report at Billing TIN level.	25,925 Billing TINs representing 140,341 eligible clinicians participating in 434 Shared Savings Program ACOs
Eligible Clinicians participating in APMs that are not Advanced APMs (other than Shared Savings Program Track 2 and 3)	APM participants in APMs other than the Shared Savings Program will report as individuals.	55,000 APM participants
Total number of entities submitting		517,425 submitting entities representing 631,931 eligible clinicians

Because Performance Year 2017 will be the first year for MIPS eligible clinicians to report the advancing care information performance category data as groups, there is considerable uncertainty about what number of MIPS eligible clinicians will report as part of a groups. For the purposes of our burden estimate, we conservatively estimate that all the clinicians that reported as individuals under the 2015 Medicare EHR Incentive Program will continue to report as individuals in MIPS Year 1, but may transition to group submission in future years. Because some participants in APM Entities will be required to report advancing care information performance category data to fulfill the requirements of submitting to MIPS, we have included them in our burden estimate for the advancing care information performance category. Further we anticipate that the 434 Shared Savings Program ACOs will submit data at the ACO participant billing TIN level, for a total of 25,925 submitting entities, and approximately 55,000 other APM participants will report as individual MIPS eligible clinicians. Hence, as shown in Table 56, we estimate that up to approximately 517,425 entities will be submitting data under the advancing care information performance category (436,100 MIPS eligible clinicians + 25,925 billing TINS within the Shared Savings Program ACOs + 55,000 APM participants). The total burden hours for a MIPS eligible clinician or group to report on the objectives and measures specified for the advancing care information performance category will be 4 hours. The total estimated burden hours are 1,552,275 (517,425 × 4). At a physician's hourly rate, the total burden cost is $283,228,097 (1,552,275,300 × $182.46).

TABLE 56: Total Estimated Burden for Advancing Care Information Performance Category Data Submission

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
517,425	517,425	4	2,069,700	$182.46	$377,637,462

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[33] We do not anticipate any changes in the CERHT process for EHR vendors as we transition to MIPS. Hence, EHR vendors are not included in these burden estimates.

G. ICRs Regarding Burden for Clinical Practice Improvement Activities Submission (§ 414.1355, § 414.1365, and Section II.E.5.d of This Preamble)

Requirements for submitting clinical practice improvement activities are new, and we do not have historical data which is directly relevant. As noted in section III.B, a variety of entities will report advancing care information performance category data on behalf of eligible clinicians. For eligible clinicians who are not part of APMs, we assume that the number of eligible clinicians submitting as part of a group will be approximately the same as the number of eligible clinicians submitting PQRS data through the GPRO Web Interface in 2014. We estimate that that there could be as many as 595,100 MIPS eligible clinicians submitting CPIA category data as individuals, which is equal to the number of eligible clinicians using the claims, QCDR or qualified registry, or EHR submission mechanisms under the 2014 PQRS.[34] We estimate that approximately 112,500 MIPS eligible clinicians comprising 300 groups may report at the group level.

TABLE 57: Estimated Numbers of Entities Submitting CPIA Category Data on Behalf of Clinicians

Category of Clinician	Available mechanisms for submission	Estimated number of entities submitting data
Eligible Clinicians (not in APMs) i	As groups or individuals.	300 groups representing 112,500 eligible clinicians 595,100 eligible clinicians submitting individually
Eligible Clinicians participating in Shared Savings Program Tracks 1, 2, and 3	Shared Savings Program participants will report at Billing TIN level.	25,925 Billing TINs representing 140,341 eligible clinicians participating in 434 Shared Savings Program ACOs
Eligible Clinicians participating in APMs (other than Shared Savings Program Track 2 and 3)	APM participants in models other than the Shared Savings Program will report as individual clinicians.	55,000 APM participants
Total number of entities submitting		676,325 Entities submitting on behalf of 903,031 eligible clinicians

Because some APM Entities and participants will be required to report CPIA data to fulfill the requirements of submitting to MIPS, we have included them in our burden estimate for the CPIA submitting. As with the advancing care information performance category, participants in Shared Savings Program ACOs will report at the ACO participant billing TIN level, and other APM participants will report as individual MIPS eligible clinicians. We anticipate MIPS eligible clinicians, groups, APM billing TINs, will submit CPIA data using the same mechanism, or a similar mechanism as they select for submitting quality data. In addition to collecting necessary supporting documentation, each MIPS eligible clinician, group, ACO participant billing TIN, or APM participant will provide a yes/no attestation submitted during the data submission period for successfully completed CPIAs. We estimate that up to approximately 676,325 entities will be submitting data for CPIA. We estimate it will take no longer than 3 hours per entity to submit data for the CPIA category. The total estimated burden is 2,028,975 (676,325 entities × 3 hours each). At a physician's hourly rate, the total estimated burden cost is $370,206,779 (2,028,975 × $182.46).

TABLE 58: Total Estimated Burden for CPIA Submission

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
676,325	676,325	3	2,028,975	$182.46	$370,206,779

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[34] Because of the lack of historical data on CPIA submission, our estimate of 595,100 eligible clinicians submitting CPIA data is based on 2014 PQRS historical data (595,100 eligible clinicians = 299,169 eligible clinicians submitting quality data through claims + 214,590 eligible clinicians submitting quality data through QCDR or qualified registry + 77,241 eligible clinicians submitting quality data through EHR).

H. ICRs Regarding Burden for Resource Use (§ 414.1350 and Section II.E.5.c of This Preamble)

The resource use performance category relies on administrative claims data. For claims-based submitting, the Medicare Parts A and B claims submission process is used to collect data on resource measures from MIPS eligible clinicians. MIPS eligible clinicians are not asked to provide any documentation by CD or hardcopy. Therefore, we do not anticipate any new or additional submitting for MIPS eligible clinicians as a result of this performance category within MIPS.

I. ICR Regarding Partial QP Elections for Advanced APMs

Section II.E.5.h. of this preamble discusses the MIPS-related submission requirements for participants in the Shared Savings Program and certain APMs. APM Entities participating in Advanced APMs will face an additional submission requirement under MIPS related to Partial Qualifying APM Participant (QP) elections. A representative from each APM Entity will log into the MIPS portal to indicate whether eligible clinicians would wish to participate in MIPS if the eligible clinicians participating in the APM Entity are later deemed to be Partial QPs. We estimate it will take each APM Entity representative 15 minutes to make this election, and an additional 15 minutes to register for the MIPS Portal. We estimate that 543 APM Entities will make this election on the MIPS Portal, for a total burden estimate of 272 hours (543 × .5). At a computer systems analyst's hourly labor cost, the total burden cost is estimated to be $22,795 (272 × $83.96).

TABLE 59: Total Estimated Burden for Partial QP Election

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
543	543	.5	272	83.96	22,795

J. Summary of Annual Burden Estimates

The total gross burden estimate includes the total burden of recordkeeping and data submission under MIPS. Table 60 provides an estimate of the total annual burden of MIPS of 12,493,654 hours and a total annual burden cost of $1,327,177,683. Some of the information collection burden under MIPS does not represent an additional burden to the public, but replaces information collection burden that existed under two of its predecessor programs, the PQRS and the Medicare EHR Incentive Program. The estimated total existing burden approved for information collections related to PQRS and the Medicare EHR Incentive Program (for EPs) was 9,969,514 hours for a total annual burden cost of $1,199,257,029. The net burden estimate reflects only the incremental burden associated with this rule, and excludes the burden of existing recordkeeping and data submission under the PQRS, the Medicare EHR Incentive Program, CAHPS for PQRS, and PQRS Data Validation.[35] Mindful of the combined data submission burden of MIPS, we have sought to avoid duplication of data submission efforts and simplified data submission structures within the unified program.

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[35] The previously approved data collections OMB control numbers were as follows: PQRS (OCN 0938–1059), CAHPS for PQRS (OCN 0938–1222), and PQRS Data Validation (OCN 0938–1255) and the Objectives/Measures (EP) ICR in the EHR Incentive Program Stage III PRA under review at OMB (OCN 0938–1278).

TABLE 60: Proposed Annual Recordkeeping and Reporting Requirements

Section(s) in title 42 of the CFR and Section of Rule	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Annual Burden Cost ($)
§414.1330 and §414.1335 (Quality Performance Category) Claims Submission Mechanism	299,169	299,169	17.8	5,325,208	Varies (see Table 47)	387,252,730
§414.1330 and §414.1335 (Quality Performance Category) Qualified Registry or QCDR Submission Mechanisms	214,590	214,590	10	2,163,711	Varies (see Table 48)	$138,734,298
§414.1330 and §414.1335 (Quality Performance Category) EHR- Submission Mechanism	77,241	77,241	11	849,651	Varies (See Table 49)	55,883,864
§414.1330 and §414.1335 (Quality Performance Category) CMS Web Interface Submission Mechanism	300	300	81	24,300	Varies (See Table 50)	2,054,850
§414.1400 (Quality Performance Category) CAHPS for MIPS	86,100	986,100	.337	29,016	23.06	669,102
§414.1400 (QCDR and Registries) QCDR and qualified registry self nomination	150	10	1500	1,500	83.96	125,940
§414.1390 (Data Validation and Auditing)	430	430	1.5	645	34.20	22,059
§414.1375 (Advancing Care Information Performance Category)	517,425	517,425	4	2,069,700	182.46	377,637,462
§414.1360 (CPIA)	676,325	676,325	3	2,028,975	182.46	370,206,779

Section(s) in title 42 of the CFR and Section of Rule	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Annual Burden Cost ($)
$414.1430 (Partial Qualifying APM Participant (QP) election)	543	543	.5	272	83.96	22,795
Total Gross Burden		1,872,273		12,492,977		1,327,162,070
Total Approved Burden Under Previous Programs		1,339,050		9,969,514		1,199,257,029
Total Net Burden		535,233		2,523,464		127,905,041

K. Submission of PRA-Related Comments

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS's Web site at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–5517–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due July 8, 2016.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the Medicare PFS and to make statutorily-required changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The MACRA's enactment consolidated certain aspects of physician quality reporting and performance programs into the new Merit-Based Incentive Payment System, including using certified EHR technology (Section 1848(o) of the Act), the PQRS (Section 1848(k) and (m) of the Act), and the value-based payment modifier (Section 1848(p) of the Act). These programs have been developed and most recently implemented by CMS as the Medicare EHR Incentive Program (80 FR 62761), the PQRS (80 FR 71135), and the VM (80 FR 71273). The MACRA's enactment altered the Medicare EHR Incentive Program such that the existing Medicare payment adjustment for EPs under section 1848(a)(7)(A) of the Act will end in CY 2018. Similarly, MACRA ends the separate PQRS Program in CY 2018 and provides for the inclusion of various aspects of PQRS in MIPS, and sunsets the VM program, ending it in CY 2018 and establishing certain aspects of the VM as a component of MIPS in CY 2019. Finally, the MACRA introduces incentive payment to eligible clinicians who become Qualifying APM Participants (QPs) through participation in Advanced APMs.

This consolidated program for physicians and other eligible clinicians represents a new approach to the delivery of health care in this care setting aimed at reducing burden on Medicare-enrolled eligible clinicians, improving population health, lowering growth in overall health care costs, and providing clear incentives for the provision of the best quality care for Medicare beneficiaries. MIPS provides payment adjustments for eligible clinicians for providing value-driven health care services to their patients, and APMs offer a variety of opportunities that substantially alter the methods of payment for health care and enable clinicians to make fundamental changes to their day-to-day operations to improve the quality and reduce the cost of health care.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 14–04), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration (SBA) standards. (For details, see the SBA's Web site at *http://www.sba.gov/content/table-smallbusiness-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a "significant economic impact on a substantial number of small entities." The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Approximately 95 percent of practitioners, other providers and suppliers are considered to be small entities, based upon the SBA standards. As shown later in this analysis, however, potential losses to these practitioners under the MIPS program are a small percentage of their total Medicare Part B PFS revenue—4 percent in the first year—though rising to as high as 9 percent in subsequent years. On average, practitioners' Medicare billings are only about 22 percent of total revenue,[36] so even those practitioners adversely affected by MIPS would rarely face losses in excess of 3 percent of revenues, the HHS standard for determining whether an economic effect is "significant." (In order to determine whether a rule meets the RFA threshold of "significant" impact HHS has for many years used as a standard adverse effects that exceed 3 percent of either revenues or costs.) However, because there are so many affected eligible clinicians, even if only a small proportion is significantly adversely affected, the number could be "substantial." Therefore, we are unable to conclude that an Initial Regulatory Flexibility Analysis (IRFA) is not required. Accordingly, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule, together meet the requirements for an IRFA. We note that whether or not a particular eligible clinician is adversely affected would depend in large part on the performance of that eligible clinician and that CMS will offer significant technical assistance to eligible clinician in meeting the new standards.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This proposed rule would impose no mandates on state, local, or tribal governments or on the private sector because participation in Medicare is voluntary and because physicians and other professionals have multiple options as to how they will participate under MIPS and discretion over their performance. Moreover, HHS interprets UMRA as applying only to "unfunded" mandates. We do not interpret Medicare payment rules as being "unfunded mandates," but simply as conditions for the receipt of payments from the Federal government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing to implement a variety of changes to our regulations, payments, or payment policies to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Medicare Payments

Section 101 of the, (1) repeals the Sustainable Growth Rate formula for physician payments in Medicare, and (2) requires that we establish a Merit-based Incentive Payment System for eligible clinician under which the Secretary must use an eligible clinician's composite performance score (CPS) to determine and apply a MIPS adjustment factor to the professional for a year.

Repealing the Sustainable Growth Rate formula eliminated significant and immediate problems with Medicare's physician fee schedule payments, including implausible payment reductions (such as the 21.2 percent decrease that was scheduled for April 1, 2015). The Office of the Actuary estimated that avoiding those payment reductions results in a budgetary cost of $150.5 billion for fiscal years 2015 through 2025 compared to the prior-law baseline. However, that cost is partially offset by other MACRA provisions that are estimated to have a net reduction in Federal expenditures of $47.7 billion.[37] The largest component of the MACRA costs is its replacement of scheduled reductions in physician payments with payment rates first frozen at 2015 levels and then increasing at a rate of 0.5 percent a year during calendar years 2016 through 2019. The estimates in this RIA take those legislated rates as the baseline for the estimates we make as to the costs, benefits, and transfer effects of the regulation, with some data collection provisions taking effect in 2017 and substantial payment reforms first taking effect in 2019.

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[36] Based on National Health Expenditure Data, Physicians and Clinical Services Expenditures, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

As required by the MACRA, overall payment rates for services for which payment is made under the PFS would remain at the 2019 level through 2025, but starting in 2019, the amounts paid to individual eligible clinicians would be subject to adjustment through one of two mechanisms, depending on whether the eligible clinician meets the threshold for participation in Advanced APMs to be considered a Qualifying APM Participant (QP) or Partial QP, or is instead evaluated under MIPS.

For APMs, from 2019 through 2024, eligible clinicians receiving a substantial portion of their revenue through Advanced APMs and meeting other applicable requirements to become QPs would receive a lump-sum payment after each year equal to 5 percent of their Medicare covered professional services for services reimbursed according to the PFS in the preceding year. The APM Incentive Payment is separate from, and in addition to, the reimbursement for services furnished by an eligible clinician during that year. Eligible clinicians who become QPs would not receive a MIPS performance adjustment under the PFS. Eligible clinicians who do not become QPs, but meet a slightly lower threshold, would be deemed Partial QPs for that year, and may elect to report to and be scored under MIPS. In QP Performance Period 2017, we define Partial QPs to be Advanced APM participants that have at least 20 percent but less than 25 percent, of their Medicare Part B payments for covered professional services through an Advanced APM Entity, or at least 10 percent, but less than 20 percent, of their Medicare patients served through an Advanced APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive or negative. If an eligible clinician does not meet either of those standards, the eligible clinician would be subject to MIPS and would report to MIPS and receive the corresponding MIPS payment adjustment.

Beginning in 2026, payment rates for eligible clinicians who achieve QP status for a year would be increased each year by 0.75 percent, while payment rates for eligible clinicians who do not achieve QP status would be increased each year by 0.25 percent. MIPS eligible clinicians would receive positive, neutral, or negative adjustments to their PFS payments in a payment year based on performance during a prior performance period. Although the legislation establishes overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the initial payment year (2019) in detail. After 2019, while overall payment levels will be partially bounded, we have also acknowledged in the preamble that the Department will revise its quality and other payment measures and overall payment thresholds and other parameters as eligible clinicians' behavior changes.

As discussed further in the preamble to this proposed rule, we are proposing requirements for MIPS that may result in the exclusion of certain eligible clinicians for various reasons. For example, MACRA requires us to exclude eligible clinicians from MIPS participation if they are QPs, or if they are a type of eligible clinician whose specialty is excluded from MIPS for the 2019 and 2020 MIPS payment years. Additionally, we are proposing above to exclude low volume eligible clinicians, or those with less than $10,000 in allowable claims and fewer than 100 Medicare patients.

We estimated the number of physicians and other professionals that would be excluded from MIPS due to their being QPs using data from APM entities that existed in 2014. First, we identified APM entities that participated in APMs that have similar design characteristics to those proposed for Advanced APMs in section II.F.4.b. of this proposed rule. In 2014, those models included the Pioneer Accountable Care Organization (ACO) Model (which is scheduled to end in 2016), Comprehensive ESRD Care (CEC) (which began in 2015, but used historical data from 2014), and Comprehensive Primary Care Initiative (CPC). Further, we assigned Shared Savings Program ACOs that existed in 2014 their 2016 track assignments because several ACOs have since transitioned to higher risk tracks. Next, we analyzed 2014 claims data to identify the APM Entities within each of those APMs to determine which of those APM Entities met the criteria for having at least 25 percent of their beneficiaries or allowable charges through the APM Entity.

Using those procedures, we arrived at a lower bound estimate that approximately 30,658 physicians and other professionals would become QPs, representing an estimated total incentive payment amount of approximately $146,000,000. However, we expect that the number of QPs may be significantly higher than the estimate based on 2014 data. CMS has continued to introduce new APMs since 2014, and intends to continue to introduce more APMs in future years. We base this expectation on prior experience with increased enrollment in current models and targets for new models that are expected to be adopted in the future. Additionally, CMS anticipates increased participation in currently existing APMs. Our upper bound estimate of QPs, based on the same estimating procedures, is 90,000 and the corresponding estimated total incentive payment is $429,000,000. In this regard, it is longstanding HHS policy not to attempt to predict the effects of future rulemakings, in order to maximize future Secretarial discretion over whether, and if so how, payment or other rules would be changed.

To estimate the number of physicians and other professionals ineligible or excluded due to the proposed low-volume exclusion, ineligible specialties, and newly-enrolled eligible clinicians, we began with a sample of clinicians participating in Medicare B in 2014.[38] We then estimated the number of ineligible clinicians by applying the low-volume exclusion proposed for MIPS—that is, eligible clinicians with less than $10,000 in allowable charges and fewer than 100 Medicare patients—and number of clinicians ineligible for MIPS in Year 1 based on their specialty. We then removed eligible clinicians that were newly enrolled in Medicare.

We have estimated the effects of these various exclusions in Table 61.

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[38] We calculated the number of eligible clinicians (at TIN–NPI level) that had positive allowable charges and a reported specialty NPPES data.

Reason for Exclusion	Number of Physicians and Other Professionals	Allowed Charges (mil) [39]
ALL	524,002-583,344	$13,909-$19,561
Qualifying APM Participants**	30,658 lower bound 90,000 upper bound	$2,919-$8,571
Ineligible Specialties***	187,990	$9,159
Newly-enrolled clinicians****	79,739	$1,137
Low-volume clinicians*****	225,615	$694

*Estimates prepared using available 2014 data.

** QPs have at least 25 percent of their Medicare payments or Medicare patients through an Advanced APM. The upper bound estimate for QPs also reflects that a small number of Advanced APM participants may be Partial QPs that opt to be excluded from MIPS. For MIPS Year 1, Partial QPs are APM participants that have at least 20%, but less than 25%, of their Medicare Part B payments for covered professional services through an Advanced APM Entity, or at least 10%, but less than 20%, of their Medicare patients served through an Advanced APM Entity

***Section 1848(q)(1)(C) of the Act defines a MIPS eligible clinician for payment years 1 and 2 as a physician, physician's assistant, nurse practitioner, or clinical nurse anesthetist, or a group that includes such clinicians.(See Section II.E.1 for further details) Our estimates of ineligible specialties count specialties not listed as eligible specialties in the Act for payment year 1 or 2: Audiologists, Certified Nurse Midwives, Clinical Psychologists/Counselors, Clinical Social Workers, Physical/Occupational Therapists, and Registered Dieticians/Nutritionists.

****Newly enrolled Medicare clinicians have allowable charges for Medicare Part B for in Calendar Year (CY) 2014 but the NPI does not have allowable charges in CY 2013.

*****Low-volume clinicians have less than $10,000 in Medicare Allowable charges and fewer than 100 Medicare patients

We have also estimated the number of clinicians[39] that we believe will be excluded from MIPS in CY 2017 by specialty. Our estimates follow in Table 62. We note that the estimates in Table 62 are based on clinicians in our 2014 data that were in ineligible specialties, newly enrolled, or met the proposed low-volume exclusion. However, due to data limitations, the estimates include only a portion of the 30,658–90,000 QPs that are listed in Table 61 above.[40]

Based on the estimates of excluded providers in Table 61, we estimate that between approximately 687,000 and 746,000 clinicians will be assigned a CPS score in MIPS Year 1.[41] They are clinicians in eligible specialties that (a) are not QPs participating in Advanced APMs (b) exceeded the low volume threshold (c) have been enrolled as Medicare physicians for more than one year, (d) had measures that met or exceeded the relevant case size thresholds.

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[39] Allowed charges only include allowed charges for covered professional services under Part B. For the QPs, the allowable charges for the lower bound were estimated using 2014 data, whereas the allowable charges for the upper bound were based on CMS projections about potential increase in APM participation.

[40] The QP estimates in Table 62 are counts of eligible clinicians that participated in the two APMs that were in effect in 2014 and meet the criteria for Advanced APMs, that is, Comprehensive Primary Care and Pioneer ACO Models. (In our 2014 data, Pioneer ACO serves as a proxy for its successor, the Next Generation ACO Model). However, due to data limitations, the QP estimate in Table 62 does not count participants in Advanced APMs that were implemented after 2014, including the Shared Savings Program Track 2 and 3, CEC, Comprehensive Primary Care Plus Model, and additional models still in development. In addition, the QP estimate in Table 62 does not count eligible clinicians that joined Advanced APMs already in existence.

[41] We estimate that 29,613 eligible clinicians with $2.443 billion in allowable charges will submit quality performance category data to MIPS but will not receive scores in quality or resource use because their measures will not meet minimum case size requirements. Because our model assigned composite performance scores using data from the quality and resource use performance categories, our model did not assign CPSs to eligible clinicians who did not meet minimum case sizes for measures in these two categories. Shared Savings Program participants were not scored on resource use, so they did not receive a composite performance score in the model if they did not meet the minimum case sizes for their quality performance category measures. However, these eligible clinicians may be scored on advancing care information and CPIA, and those two performance categories could not be modeled at this time given limited historical data.

TABLE 62: PROJECTED NUMBER OF CLINICIANS EXCLUDED FROM MIPS IN CY 2019, BY SPECIALTY*

Clinician Type	Number of Clinicians	Allowed Charges (mil)	Specialty's Allowed Charges as Percentage of Allowed Charges From All Excluded Clinicians
ALL	**540,058**	**$14,816**	**100%**
Allergy/Immunology	877	$16	<1%
Anesthesiology	15,078	$242	2%
Audiology**	7,386	$60	<1%
Cardiology	5,488	$208	1%
Certified Nurse Midwives**	2,272	$3	<1%
Chiropractor	25,524	$167	1%
Clinical Nurse Specialists	1,257	$9	<1%
Colon/Rectal Surgery	163	$4	<1%
Counselor/Clinical Psychologist**	34,016	$769	5%
Critical Care	592	$15	<1%
Dentist	2,277	$10	<1%
Dermatology	2,223	$176	1%
Dietitian/Nutritionist**	3,196	$16	<1%
Emergency Medicine	20,753	$244	2%
Endocrinology	990	$18	<1%
Family Practice	28,966	$325	2%
Gastroenterology	1,849	$43	<1%
General Practice	2,611	$19	<1%
General Surgery	5,090	$84	1%
Geriatrics	955	$24	<1%
Hand Surgery	255	$7	<1%
Infectious Disease	1,174	$30	<1%
Internal Medicine	24,831	$500	3%
Interventional Radiology	736	$31	<1%
Missing	2,263	$88	1%
Nephrology	1,739	$166	1%
Neurology	3,425	$83	1%
Neurosurgery	847	$21	<1%

Clinician Type	Number of Clinicians	Allowed Charges (mil)	Specialty's Allowed Charges as Percentage of Allowed Charges From All Excluded Clinicians
Nuclear Medicine	221	$7	<1%
Nurse Anesthetist	23,547	$206	1%
Nurse Practitioner	45,318	$335	2%
Obstetrics/Gynecology	14,318	$68	<1%
Oncology/Hematology	1,825	$46	<1%
Ophthalmology	3,792	$238	2%
Optometry	17,420	$182	1%
Oral/Maxillofacial Surgery	238	$1	<1%
Orthopedic Surgery	3,654	$69	<1%
Other Eligible Clinician	42,983	$4,345	29%
Other MD/DO	3,756	$75	1%
Otolaryngology	1,703	$47	<1%
Pathology	6,533	$340	2%
Pediatrics	7,465	$10	<1%
Physical Medicine	2,358	$100	1%
Physical/Occupational Therapy**	56,517	$2,476	17%
Physician Assistant	31,333	$188	1%
Plastic Surgery	1,310	$25	<1%
Podiatry	3,143	$95	1%
Psychiatry	12,471	$84	1%
Pulmonary Disease	1,969	$79	1%
Radiation Oncology	1,281	$308	2%
Radiology	14,319	$486	3%
Registered Nurse	1,692	$15	<1%
Rheumatology	816	$23	<1%
Social Worker**	35,783	$383	3%
Thoracic/Cardiac Surgery	571	$25	<1%
Urology	1,754	$44	<1%
Vascular Surgery	558	$48	<1%

* Estimates prepared using available 2014 data.

**All physicians and other professionals in these specialties are ineligible to participate in MIPS.

According to National Health Expenditure data,[42] in 2013, physicians and other professionals received a total of $586.7 billion from all sources. Medicare paid $130.3 billion of that amount. Based on the lower bound total in Table 61 of $13,909 billion in allowed charges for professionals excluded from MIPS, we estimate that less than 11 percent of professionals' Medicare Part B spending for services covered under the Medicare PFS will be excluded from MIPS, and less than 3 percent of all professionals' spending from all sources will be excluded.

We used 2014 VM, PQRS, and other available data to model the scoring provisions described in this regulation. First, we arithmetically calculated a hypothetical CPS for each eligible clinician. Then, we implemented an exchange function based on the provisions of this proposed rule to translate the hypothetical CPS into a negative payment adjustment or positive payment adjustment. This entailed modifying parameters of the exchange function iteratively in order to achieve distributions in payment adjustments that meet requirements related to budget neutrality and aggregate exceptional performance payment amounts. However, because of the lack of historical data for the proposed advancing care information and CPIA measures, this version of the model does not estimate scores for the advancing care information and CPIA performance categories. Based on 2015 Medicare EHR Incentive Program data, we estimate that approximately 226,514 Medicare attesters would receive a 90 percent score in the advancing care information performance category and thereby receive an estimated 23 more points to their CPS, and that 209,000 eligible clinicians receiving a negative adjustment for 2016 would receive an advancing care information performance category score of 0. We also estimate that approximately 412,678 clinicians are non-eligible provider types, and therefore, would not be measured on the advancing care information performance category. Hence we estimate the CPS using only quality and resource use performance category scores, but recognize the scores would adjust by the advancing care information characteristic estimates described above. The model also set a hypothetical performance threshold, and estimated a MIPS payment adjustment associated with each CPS.[43]

The costs for implementation and complying with the advancing care information performance category requirements could potentially lead to higher operational expenses for MIPS eligible clinicians. However, we believe that the combination of payment adjustments and long-term overall gains in efficiency will likely offset the initial expenditures. Additionally, because we are proposing above to reweight the advancing care information performance category scores for eligible clinicians that were exempt from the Medicare EHR Incentive Program or received hardship exemptions, these proposals would not impose additional requirements for EHR adoption during the first MIPS performance period. Health IT vendor may face additional costs in the first year of MIPS if they choose to develop additional capabilities in their systems in order to submit advancing care information and CPIA performance category data on behalf of eligible clinicians.

Additionally, we believe a majority of MIPS eligible clinicians who are able to report the advancing care information performance category of MIPS have already adopted an EHR during Stage 1 and 2 of the prior Medicare EHR Incentive Program. As we have stated with respect to the Medicare EHR Incentive Program, we believe that future retrospective studies on the costs to implement an EHR and the return on investment (ROI) will demonstrate efficiency improvements that offset the actual costs incurred by eligible clinicians participating in MIPS and specifically in the advancing care information performance category, but we are unable to quantify those costs and benefits at this time.

At present, evidence on EHR benefits in either improving quality of care or reducing health care costs is mixed. This is not surprising since the adoption of EHR as a fully functioning part of medical practice is still in its infancy. Even physician offices and hospitals that can meet Medicare EHR Incentive Program standards have not necessarily fully implemented all the functionality of their systems or fully exploited the diagnostic, prescribing, and coordination of care capabilities that these systems promise. Moreover, many of the most important benefits of EHR depend on interoperability among systems and this functionality is still lacking in many EHR systems. A recent RAND report prepared for the ONC reviewed 236 recent studies that related the use of health IT to quality, safety, and efficacy in ambulatory and non-ambulatory care settings and found that—

> A majority of studies that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. These studies evaluated several forms of health IT: metrics of satisfaction, care process, and cost and health outcomes across many different care settings. The relationship between health IT and [health care] efficiency is complex and remains poorly documented or understood, particularly in terms of healthcare costs, which are highly dependent upon the care delivery and financial context in which the technology is implemented. [44]

Other recent studies have not found definitive quantitative evidence of benefits.[45] We request comments providing better evidence concerning EHR benefits in reducing the costs or increasing the value of EHR-supported health care.

Similarly, the costs for implementation and complying with the CPIA performance category requirements could potentially lead to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for CPIA will vary across practices, including for some activities or patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per member per month. Costs may vary based on panel size and location of practice among other variables. For example, Magill (2015), conducted a study of PCMH in two states.[46] Magill (2015), found that costs associated with a full-time equivalent primary care clinician, who were associated with PCMH functions, varied across practices. Specifically, Magill (2015) found an average of $7,691 per month in Utah practices, and an average of $9,658 in Colorado practices.

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[42] Physicians and Clinical Services Expenditures, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

[43] The model assigned the following weights were assigned to the quality and resource use categories in estimating the composite performance score. If an eligible clinician had a valid score in both the quality performance and resource use categories, then the quality measure would be assigned a maximum of 50 points, and the resource use measure 10 points. If one category was missing, the other category was assigned its weight.

[44] Paul G. Shekelle, *et al. Health Information Technology: An Updated Systematic Review with a Focus on Meaningful Use Functionalities.* RAND Corporation. 2014.

[45] See, for example, Saurabh Rahurkar, *et al,* "Despite the Spread of Health Information Exchange, There Is Little information Of Its Impact On Cost, Use, And Quality Of Care," *Health Affairs,* March 2015; and Hemant K. Bharga and Abhay Nath Mishra, "Electronic Medical Records and Physician Productivity: Evidence from Panel Data Analysis," *Management Science,* July 2014.

[46] Magill et. al. "The Cost of Sustaining a Patient-Centered Medical Home: Experience from 2 States." *Annals of Family Medicine,* 2015; 13:429–435.

Consequently, PCMH incremental costs per encounter were $32.71 in Utah and $36.68 in Colorado (Magill, 2015). Magill (2015) also found that the average estimated cost per member, per month, for an assumed panel of 2,000 patients was $3.85 in Utah and $4.83 in Colorado. However, given the lack of comprehensive historical data for proposed CPIA, we are unable to quantify those costs in detail at this time. We request public comments on the costs associated with CPIA from practices that have implemented clinical practice improvements in the past.

Payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual eligible clinician could vary from the average and would depend on the mix of services that the eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because eligible clinicians generally furnish services to both Medicare and non-Medicare patients. In addition, eligible clinicians may receive substantial Medicare revenues for services under other Medicare payment systems that would not be affected by MIPS adjustment factors.

Table 63 shows the estimated payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 63. We conducted sensitivity analyses with low, high, and midpoint estimates, and we believe the midpoint estimate represents our best projection of the effects of the MIPS program on Medicare charges. As noted above, given the limitations on the data used for this simulation, differences between specialties are attributable to different performance levels on the quality and resource use performance category measures available from historical PQRS and VM data. Our midpoint estimate, with a performance threshold set at 50, follows as Table 63.[47] Additionally, using the same data, we have estimated the impact on PFS services of the proposals contained in this proposed rule by practice size. That estimate follows as Table 64.

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[47] Note to reviewers: This analysis has been updated with the latest estimates.

TABLE 63: MIPS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY: MID-POINT ESTIMATE*

Provider Type	Number of Physicians and Other Clinicians	Allowed Charges (mil)	Percent with negative payment adjustment	Percent with positive payment adjustment	Aggregate Impact Negative Payment Adjustment (mil)*	Aggregate Impact Positive Adjustment (mil)	Aggregate Positive Adjustment, Excluding Exceptional Performance Payment (mil)	Aggregate Positive Adjustment, Exceptional Performance Payment Only (mil)
ALL[48]	761,342	$72,606	45.5%	54.1%	-$833	$1,333	$833	$500
Allergy/Immunology	3,031	$199	57.1%	42.6%	-$4	$3	$2	$1
Anesthesiology	34,233	$1,904	47.4%	52.2%	-$25	$29	$18	$11
Cardiology	29,176	$5,791	37.5%	62.1%	-$35	$127	$80	$47
Chiropractic	20,572	$585	98.4%	1.5%	-$22	$0	$0	$0
Clinical Nurse Specialists	1,681	$57	54.7%	44.9%	-$1	$1	$0	$0
Colon/Rectal Surgery	1,244	$136	40.0%	59.7%	-$1	$3	$2	$1
Critical Care	2,550	$265	46.3%	53.5%	-$4	$4	$2	$1
Dentist	915	$26	68.9%	30.1%	-$1	$0	$0	$0
Dermatology	10,317	$2,824	42.2%	57.6%	-$21	$92	$55	$37
Emergency Medicine	41,728	$2,626	35.4%	64.0%	-$19	$53	$33	$20
Endocrinology	5,401	$445	32.6%	67.3%	-$3	$10	$6	$4
Family Practice	79,541	$5,666	40.2%	59.5%	-$60	$103	$65	$38

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[48] Due to limitations in scoring model data, the number of clinicians in the sample for Table 63 (761,342) exceeds our upper bound estimate of the number of eligible clinicians that will receive composite performance scores for MIPS Year 1 (746,000). The upper bound estimate of the number eligible clinicians that would receive composite performance scores excludes clinicians that participated in the two APMs that were in effect in 2014 and met the criteria for Advanced APMs. In our scoring model data, we could not identify and exclude eligible clinicians that would begin participating in existing or new Advanced APMs after 2014.

Provider Type	Number of Physicians and Other Clinicians	Allowed Charges (mil)	Percent with negative payment adjustment	Percent with positive payment adjustment	Aggregate Impact Negative Payment Adjustment (mil)*	Aggregate Impact Positive Adjustment (mil)	Aggregate Positive Adjustment, Excluding Exceptional Performance Payment (mil)	Aggregate Positive Adjustment, Exceptional Performance Payment Only (mil)
Gastroenterology	12,608	$1,639	38.3%	61.5%	-$16	$34	$21	$13
General Practice	3,598	$273	69.4%	30.3%	-$5	$2	$1	$1
General Surgery	20,387	$1,926	45.5%	54.2%	-$24	$35	$22	$13
Geriatrics	3,790	$447	48.3%	51.6%	-$7	$7	$4	$3
Hand Surgery	1,779	$230	48.7%	51.1%	-$3	$4	$3	$2
Infectious Disease	5,544	$644	42.9%	56.9%	-$12	$9	$5	$3
Internal Medicine	89,257	$9,327	40.3%	59.4%	-$101	$176	$110	$66
Interventional Radiology	1,780	$337	40.4%	59.2%	-$4	$6	$4	$2
Nephrology	8,497	$2,065	41.6%	58.0%	-$19	$37	$23	$14
Neurology	13,000	$1,248	40.6%	59.2%	-$15	$24	$15	$9
Neurosurgery	4,489	$689	43.8%	55.6%	-$8	$12	$8	$5
Nuclear Medicine	626	$100	44.2%	55.0%	-$2	$2	$1	$1
Nurse Anesthetist	31,737	$826	51.1%	48.4%	-$14	$9	$6	$3
Nurse Practitioner	50,764	$1,626	37.7%	62.0%	-$25	$27	$17	$10
Obstetrics/Gynecology	21,650	$538	38.8%	61.1%	-$8	$10	$6	$4
Oncology/Hematology	11,705	$1,706	37.5%	62.1%	-$13	$24	$15	$9
Ophthalmology	17,259	$5,060	44.8%	54.7%	-$43	$114	$71	$43
Optometry	18,394	$945	79.7%	20.2%	-$21	$10	$6	$4

Provider Type	Number of Physicians and Other Clinicians	Allowed Charges (mil)	Percent with negative payment adjustment	Percent with positive payment adjustment	Aggregate Impact Negative Payment Adjustment (mil)*	Aggregate Impact Positive Adjustment (mil)	Aggregate Positive Adjustment, Excluding Exceptional Performance Payment (mil)	Aggregate Positive Adjustment, Exceptional Performance Payment Only (mil)
Oral/Maxillofacial Surgery	200	$7	55.0%	44.5%	$0	$0	$0	$0
Orthopedic Surgery	20,277	$3,254	46.4%	53.3%	-$33	$63	$40	$24
Other MD/DO	10,674	$1,117	42.9%	56.7%	-$15	$20	$12	$7
Otolaryngology	8,211	$1,015	47.4%	52.3%	-$13	$18	$11	$7
Pathology	7,302	$593	43.3%	56.7%	-$9	$10	$6	$4
Pediatrics	4,589	$55	20.6%	79.3%	-$1	$1	$1	$0
Physical Medicine	7,295	$918	57.9%	41.9%	-$17	$12	$8	$5
Physician Assistant	43,994	$1,212	32.5%	67.1%	-$13	$26	$16	$10
Plastic Surgery	3,691	$287	65.4%	34.5%	-$7	$4	$2	$1
Podiatry	15,310	$1,882	78.0%	21.8%	-$46	$14	$9	$5
Psychiatry	20,854	$1,143	68.8%	31.1%	-$29	$8	$5	$3
Pulmonary Disease	10,493	$1,655	41.9%	57.8%	-$20	$26	$17	$10
Radiation Oncology	4,239	$1,513	44.2%	55.4%	-$16	$27	$17	$10
Radiology	34,998	$4,165	49.2%	50.4%	-$49	$65	$41	$24
Registered Nurse	1,942	$58	49.3%	50.4%	-$1	$1	$0	$0
Rheumatology	4,274	$495	32.2%	67.6%	-$3	$13	$8	$5
Thoracic/Cardiac Surgery	3,688	$596	37.7%	61.8%	-$5	$11	$7	$4
Urology	8,814	$1,586	40.5%	59.2%	-$13	$31	$19	$11
Vascular Surgery	3,244	$906	42.4%	57.2%	-$10	$18	$11	$7

*2014 data used to estimate 2017 performance. Payments estimated using 2014 dollars.

TABLE 64: MIPS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY PRACTICE SIZE*

Practice Size	Eligible Clinicians	Physician Fee Schedule Allowed Charges ($ Mil)	Percent Eligible Clinicians with Negative Adjustment	Eligible Clinicians with Negative Adjustment	Percent Eligible Clinicians with Positive Adjustment	Eligible Clinicians with Positive Adjustment	Eligible Clinicians with no Adjustment	Aggregate impact Negative Payment Adjustment ($ Mil)	Aggregate Impact Positive Adjustment ($ Mil)	Aggregate Positive Adjustment, excluding exceptional Performance Payment ($ Mil)	Aggregate Positive Adjustment, exceptional Performance Payment only ($ Mil)
Solo	102,788	$12,458	87.0%	89,383	12.9%	13,302	103	-$300	$105	$65	$40
2-9 eligible clinicians	123,695	$18,697	69.9%	86,519	29.8%	36,887	289	-$279	$295	$182	$113
10-24 eligible clinicians	81,207	$9,934	59.4%	48,213	40.3%	32,737	257	-$101	$164	$103	$61
25-99 eligible clinicians	147,976	$12,868	44.9%	66,515	54.5%	80,588	873	-$95	$230	$147	$84
100 or more eligible clinicians	305,676	$18,648	18.3%	56,045	81.3%	248,626	1,005	-$57	$539	$336	$203
Overall	**761,342**	**$72,606**	**45.5%**	**346,675**	**54.1%**	**412,140**	**2,527**	**-$833**	**$1,333**	**$833**	**$500**

*2014 data used to estimate 2017 performance. Payments estimated using 2014 dollars.

Based on National Health Expenditure data,[49] total Medicare payments for physicians and clinical services expenditures in 2013 reached $130.3 billion. Payments from all sources reached $586.7 billion. Table 63 shows that the aggregate negative payment adjustment for all eligible clinicians under MIPS is estimated at $833 million, which represents less than 1 percent of eligible clinicians' Medicare payments and less than 0.2 percent of eligible clinicians' payments from all sources. Table 63 also shows that the aggregate positive payment adjustment for eligible clinicians under MIPS is estimated at $1.333 billion (including exceptional performance adjustments), which represents approximately 1.02 percent of eligible clinicians' Medicare payments and 0.23 percent of payments from all sources.

D. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that the proposed changes will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

More broadly, we expect that over time both the overall MIPS program and increasing participation in APMs will increasingly result in improved quality of care, resulting in lower morbidity and mortality, and in reduced spending, as physicians respond to the incentives offered by MIPS and APMs and adjust their clinical practices in order to maximize their performance on specified quality measures and activities. The various shared savings initiatives already operating have had modest success but have demonstrated that all three outcomes are possible. For example, in August of 2015, we issued 2014 quality and financial performance results showing that Medicare ACOs continue to improve the quality of care for Medicare beneficiaries while generating financial savings.[50] Additionally, in their first years of implementation, both Pioneer and Shared Savings Program ACOs had higher quality care than Medicare fee for service (FFS) providers on measures for which comparable data were available. Shared Savings Program patients with multiple chronic conditions and with high predicted Medicare spending received better quality care than comparable FFS patients.[51] Between the first and third performance periods, Pioneer ACOs improved their average quality score from 73 percent to 87 percent. Taken together, Pioneer and Shared Savings Program ACOs yielded $411 million in cost savings in 2014.[52]

Results from the first year of the CPC Initiative indicate that it has generated nearly enough savings in Medicare health care expenditures to offset care management fees paid by CMS.

- The primary sources of the savings were reduced rates of hospital admissions and emergency department visits.
- The bulk of the savings was generated by patients in the highest-risk quartile, but favorable results were also seen in other patients.
- Over 90 percent of practices successfully met all first-year transformation requirements.
- The expenditure impact estimates differ across the seven regions.
- Additional time and data are needed to assess impact on care quality.

These results should be interpreted cautiously as effects are emerging earlier than anticipated, and additional research is needed to assess how the initiative affects cost and quality of care beyond the first year. Because the effects of the CPC Initiative are likely to be larger in subsequent years, these early results suggest it is likely the model will eventually break-even or generate savings.[53]

Basing reimbursement in part on performance metrics is still an evolving art and, as discussed throughout this preamble, there are multiple variables and as yet no definitive answers as to what combinations of measures, benchmarks, and other variables will achieve the best results over time. Accordingly, we are unable at this time to provide specific dollar estimates of these benefits and cost reductions.

E. Impact on Other Health Care Programs and Providers

The MIPS program is aimed at Medicare FFS physicians and other professionals paid under the PFS. These physicians and other professionals are almost all engaged in serving patients covered by other payers as well. Because Medicare covers only about one person in seven (though a considerably higher share of total healthcare spending, since older persons incur far higher expenses on average than younger persons), for most of those services that will be subject to MIPS payment adjustments, Medicare provides only a fraction of practice revenues. Moreover, it is unlikely that many insurance payers will adopt MIPS or MIPS-like payment models in the short run. Hence, MIPS incentives are necessarily attenuated. On the other hand, changing practices for one group of patients will possibly lead to changes for other patients (for example, EHR systems are almost always used for all patients served by a physician). Physicians and other professionals may find it simpler and more efficient to adopt clinical practice improvements for all patients, regardless of payer, in response to MACRA's incentives, through the use of both MIPS measures and activities and alternative payment models. Furthermore, since MACRA eventually rewards participation in APMs beyond those in Medicare, other payers may start to develop more models in which clinicians and patients can participate. Hence, there are likely to be beneficial effects on a far broader range of patients in the health care system than simply Medicare patients, and we believe those effects would include improved health care quality and lower costs over time. However, we have no basis at this time for quantifying such effects.

We note that large proportions of the Medicare and Medicaid programs are already delivered through capitated insurance payments to HMOs, PPOs, and related organizations. The Medicare Advantage program and related State programs therefore already have substantial incentives to improve quality and reduce costs. MIPS does not affect provider payments under those programs directly, which have their own reimbursement mechanisms for physicians and other professionals. In many but not all cases, those insurance carriers do use incentive mechanisms that are similar in purpose and design to the kinds of APMs that we expect will arise under the new payment adjustments. We would not expect major near-term changes in HMO and PPO payment arrangements, or performance, from any MIPS or APM spillover effects. Regardless, we have no basis at this time for quantifying any such effects.

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[49] Physicians and Clinical Services Expenditures, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

[50] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-25.html.*

[51] J. M. McWilliams et al., "Changes in Patients' Experiences in Medicare Accountable Care Organizations." New England Journal of Medicine 2014; 371:1715–1724, DOI: 10.1056/NEJMsa1406552.

[52] The cost savings were for the second year of Shared Savings Program implementation and the third year of Pioneer ACO implementation. *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-25.html.*

[53] *https://blog.cms.gov/2015/01/23/moving-forward-on-primary-care-transformation/.* For more detail see *https://innovation.cms.gov/files/reports/cpci-evalrpt1.pdf.*

There are other potentially affected provider entities, including hospitals, skilled nursing facilities, Critical Access Hospitals (largely small rural hospitals), and providers serving unique populations, such as providers of tribal health care services. In none of these cases do we believe that MIPS would have significant effects on substantial numbers of providers. But to the extent that MIPS and increasing participation in APMs over time succeed in improving quality and reducing costs, there may be some beneficial effects not only on patients but also on some providers.

As noted previously in this section of the preamble, and as discussed in this subsection, we have concluded that financial effects on either directly or indirectly affected small entities, including rural hospitals, will be minimal. We welcome comments on these conclusions.

F. Alternatives Considered

This proposed rule contains a range of policies, including many provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies where discretion has been exercised, presents our rationale for our proposed policies and, where relevant, analyzes alternatives that we considered. While it is hard to single out any one alternative for public comment, we particularly call attention to the performance threshold and the level at which it is set for scoring purposes under MIPS.

As described above, pursuant to section 1848(q)(6)(D)(i) of the Act, for each year of the MIPS, the Secretary shall compute a performance threshold with respect to which the CPSs of MIPS eligible clinicians are compared for purposes of determining the MIPS adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, which may be reassessed every 3 years) of the CPSs for all MIPS eligible clinicians for a prior period specified by the Secretary. Section 1848(q)(6)(D)(iii) of the Act outlines a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS adjustment factors under paragraph (A) and an additional performance threshold for purposes of determining the additional MIPS adjustment factors under paragraph (C), each of which shall be based on a period prior to the performance periods and take into account data available with respect to performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary.

Depending on where the threshold is set within those parameters, the proportions and distributions of MIPS eligible clinicians receiving payment reductions versus positive payment adjustments can change dramatically from our estimates. For example, in Table 63, we estimated (based on available data) that 40.0 percent of Colon/Rectal Surgery specialists will receive a negative payment adjustment under MIPS. Setting the performance threshold at a lower level would enable more Colon/Rectal Surgery specialists to avoid negative adjustments and potentially qualify for more positive adjustments. Conversely, we estimated above that 59.2 percent of Interventional Radiology specialists would receive a positive adjustment under the current proposal. Setting the performance threshold at a higher level would result in fewer Interventional Radiology specialists qualifying for positive adjustments, and potentially more of them receiving negative adjustments. But any payment changes resulting from changes to the performance threshold policy will depend primarily on changes to practices and other responses from MIPS eligible clinicians.

We request comment on these alternatives, on all previous estimates of effects, and on any other issues or options that might improve the substantive effects of this proposed rule, or our estimates of those effects. We are particularly interested in comments on any aspects of this proposed rule that might inadvertently or unintentionally create adverse effects on the delivery of high quality and high value health care, and on options that might reduce such effects.

G. Assumptions and Limitations

We would like to note several limitations to the analyses that estimated eligible clinicians' eligibility, negative payment adjustments, and positive payment adjustments based for the first MIPS performance period (2017) based on 2014 data described above:

- *The scoring model cannot reflect that eligible clinicians' behavioral responses to MIPS will be different than their responses to the 2014 PQRS requirements.* As with all scoring models based on historical data, the model assumes that the measures reported and the distribution of scores on those measures would be the same under MIPS' first performance period as they were under the 2014 PQRS program. However, the intent of the MIPS program is to incentivize eligible clinicians both in terms of the reporting of measures and in terms of improving the quality of patient care.
- *Limited historical data for two performance categories.* Because we have limited historical data for the proposed advancing care information and CPIA performance categories, the modeled scoring estimates do not include advancing care information or CPIA performance category scores. The model also set a hypothetical performance threshold and estimated a MIPS payment adjustment for each CPS.
- *Some of the MIPS scoring provisions could not be applied because MIPS will have different reporting requirements than PQRS.* For example, the proposed MIPS scoring provisions require at least one cross-cutting quality measure, whereas the 2014 PQRS program did not have such a requirement.
- *The scoring model does not reflect the growth in Advanced APM participation between 2014 and 2017.* Due to data limitations, the scoring model could only identify clinicians that participated in Advanced APMs and would have exceeded the QP threshold in 2014. Several new Advanced APM have been implemented or will be implemented between 2014 and 2017. Further, some clinicians will join the successors of Advanced APMs already in existence in 2014.

Due the limitations above, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 65 (Accounting Statement), we have prepared an accounting statement.

We have not attempted to quantify the benefits of this rule because of the many uncertainties as to both provider behaviors and resulting effects on patient health and cost reductions. For example, the applicable percentage for MIPS incentives changes over time, increasing from 4 percent in 2019 to 9 percent in 2022 and subsequent years, and we are unable to estimate precisely how physicians will respond to the increasing incentives. As noted above, in CY 2019, we estimate that we will distribute approximately $833 million in payment adjustments on a budget-neutral basis, which represents the applicable percent for 2019 required under section 1848(q)(6)(B)(i) of the Act and excludes $500 million in exceptional performance payments. In 2020, section 1848(q)(6)(B)(ii) of the Act specifies that the applicable percent will be 5 percent, which we estimate would mean that we will distribute approximately $1,041 million in payment adjustments on a budget-neutral basis, ignoring changes in clinical practice, volume growth, or other changes that may affect Medicare physician payments. Finally, in 2021, section 1848(q)(6)(B)(iii) of the Act specifies that the applicable percent will be 7 percent, which we estimate would mean that we will distribute approximately $1,458 million in payment adjustments on a budget-neutral basis, again ignoring changes in clinical practice, volume growth, or other changes that may affect Medicare physician payments, as well as the $500 million in exceptional performance payments.

Further, the addition of new APMs and participants over time will affect the pool of MIPS eligible clinicians, and for those that are MIPS eligible clinicians, may change their relative performance. The $500 million available for exceptional performance and the 5 percent incentive for QPs are only available from 2019 through 2024. Beginning in 2026, QPs will receive a higher conversion factor than non-QPs. However, we are unable to estimate the number of QPs in those years, as we cannot project the number or types of Advanced APMs that will be made available in those years through future CMS initiatives proposed and implemented in those years, nor the number of QPs for those models.

The percentage of the CPS attributable to each performance category will change over time, and we will incorporate improvement scoring in future years. The CPIA category represents an entirely new category for measuring eligible clinicians' performance. We may also propose policy changes in future years as we continue implementing MIPS and as eligible clinicians accumulate experience with the new system. Moreover, there are interactions between the MIPS and APM incentive programs and other shared savings and incentive programs that we cannot model or project. Nonetheless, even if ultimate savings and health benefits represent only low fractions of current experience, benefits are likely to be substantial in overall magnitude.

The table that follows includes our estimate for MIPS payment adjustments ($833 million), the exceptional performance payments under MIPS ($500 million), and payments to QPs (using the lower bound estimate described in the preceding analysis, $146 million). However, of these three elements, only the budget-neutral MIPS payment adjustments are shown as estimated decreases.

TABLE 65: Accounting Statement

Category	Transfers
CY 2019 Annualized Monetized Transfers....	Estimated increase of $1,479 million in payments for higher performance under MIPS and APM Incentive Payments.
From Whom to Whom?................................	Increased Federal Government payments to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
Category	**Transfers**
CY 2019 Annualized Monetized Transfers....	Estimated decrease of $883 million for lower performance under MIPS.
From Whom to Whom?................................	Reduced Federal Government payments to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

Note: these estimates are identical under both a 7 percent and 3 percent discount rate.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

§ 414.90 [Amended]

■ 2. In § 414.90—

■ a. Amend paragraph (e) introductory text by removing the phrase "and subsequent years" and adding in its place the phrase "through 2018".

■ b. Amend paragraph (e)(1)(ii) by removing the phrase "and each subsequent year" and adding in its place the phrase "through 2018".

■ 3. Subpart O is added to part 414 to read as follows:

Subpart O—Merit-Based Incentive Payment System and Alternative Payment Model Incentive

Sec.
414.1300 Basis and scope.
414.1305 Definitions.
414.1310 Applicability.
414.1315 [Reserved]
414.1320 MIPS performance period.
414.1325 Data submission requirements.
414.1330 Quality performance category.
414.1335 Data submission criteria for the quality performance category.
414.1340 Data completeness criteria for the quality performance category.
414.1350 Resource use performance category.
414.1355 Clinical practice improvement activity performance category.
414.1360 Data submission criteria for the clinical practice improvement activity performance category.
414.1365 Subcategories for the clinical practice improvement activity performance category.
414.1370 APM scoring standard for MIPS.
414.1375 Advancing care information performance category.
414.1380 Scoring.
414.1385 Targeted review and review limitations.
414.1390 Data validation and auditing.
414.1395 Public reporting.
414.1400 Third party data submission.
414.1405 Payment.
414.1410 Advanced APM determination.
414.1415 Advanced APM criteria.
414.1420 Other payer advanced APMs.
414.1425 Qualifying APM participant determination: In general.
414.1430 Qualifying APM participant determination: QP and partial QP thresholds.
414.1435 Qualifying APM participant determination: Medicare option.
414.1440 Qualifying APM participant determination: All-payer combination option.
414.1445 Identification of other payer advanced APMs.
414.1450 APM incentive payment.
414.1455 Limitation on review.
414.1460 Monitoring and program integrity.
414.1465 Physician-focused payment models.

Subpart O—Merit-Based Incentive Payment System and Alternative Payment Model Incentive

§ 414.1300 Basis and scope.

(a) *Basis.* This subpart implements the following provisions of the Act:

(1) Section 1833(z)—Incentive Payments for Participation in Eligible Alternative Payment Models.

(2) Section 1848(a)—Payment Based on Fee Schedule.

(3) Section 1848(k)—Quality Reporting System.

(4) Section 1848(q)—Merit-Based Incentive Payment System.

(b) *Scope.* This subpart part sets forth the following:

(1) The circumstances under which eligible clinicians are not considered MIPS eligible clinicians with respect to a year.

(2) How individual MIPS eligible clinicians can have their performance assessed as a group.

(3) The data submission methods and data submission criteria for each of the MIPS performance categories.

(4) Methods for calculating a performance category score for each of the MIPS performance categories.

(5) Methods for calculating a MIPS composite performance score and applying the MIPS payment adjustment to MIPS eligible clinicians.

(6) The elements an APM must require of its participants to be designated an "Advanced APM."

(7) Methods for how eligible clinicians and entities participating in Advanced APMs can meet the participation thresholds to become Qualifying APM Participants (QPs) and Partial QPs.

(8) Methods and processes for counting participation in certain other payer arrangements (Other Payer Advanced APMs) in making QP and Partial QP determinations.

(9) Methods for calculating and paying the APM Incentive Payment to QPs.

(10) Evaluation of stakeholder submissions of Physician-Focused Payment Models (PFPMs).

§ 414.1305 Definitions.

As used in this section, unless otherwise indicated—

Additional performance threshold means an additional level of performance, in addition to the performance threshold, for a performance period at the composite level at or above which a MIPS eligible clinician may receive an additional positive MIPS adjustment factor.

Advanced Alternative Payment Model (Advanced APM) means an APM that CMS determines meets the criteria set forth in § 414.1415.

Advanced APM Entity means an APM entity that participates in an Advanced APM or Other Payer Advanced APM through a direct agreement with CMS or a non-Medicare other payer, respectively.

Affiliated practitioner means an eligible clinician identified by a unique APM participant identifier on a CMS-maintained list who has a contractual relationship with the Advanced APM Entity based at least in part on supporting the Advanced APM Entity's quality or cost goals under the Advanced APM.

Alternative Payment Model (APM) means any of the following:

(1) A model under section 1115A of the Act (other than a health care innovation award).

(2) The shared savings program under section 1899 of the Act.

(3) A demonstration under section 1866C of the Act.

(4) A demonstration required by Federal law.

APM Entity means an entity that participates in an APM or Other Payer APM through a direct agreement with CMS or a non-Medicare other payer, respectively.

APM Entity group means the group of eligible clinicians participating in an APM Entity, as identified by a combination of the APM identifier, APM Entity identifier, Taxpayer Identification Number (TIN), and National Provider Identifier (NPI) for each participating eligible clinician.

APM Incentive Payment means the lump sum incentive payment paid to Qualifying APM Participants.

Attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the advancing care information and/or CPIA performance categories of MIPS in a manner specified by CMS.

Attributed beneficiary means a beneficiary attributed, according to the Advanced APM's attribution rules, to the Advanced APM Entity on the latest available list of attributed beneficiaries during the QP Performance Period.

Attribution-eligible beneficiary means a beneficiary who during the QP performance period:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan,

(2) Does not have Medicare as a secondary payer,

(3) Is enrolled in both Medicare Parts A and B,

(4) Is at least 18 years of age,

(5) Is a United States resident, and

(6) Has a minimum of one claim for evaluation and management services furnished by an eligible clinician in the APM Entity group for any period during the QP Performance Period. For APMs that CMS determines to be focused on specific specialties or conditions or to have an attribution methodology that is not based on evaluation and management services, CMS uses a comparable standard related to the APM-specific attribution methodology for identifying beneficiaries as potential candidates for attribution.

Certified electronic health record technology (CEHRT) means the following:

(1) For any calendar year before 2018, EHR technology (which could include

multiple technologies) certified under the ONC Health IT Certification Program that meets one of the following:

(i) The 2014 Edition Base EHR definition (as defined at 45 CFR 170.102) and that has been certified to the certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS advancing care information performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(ii) Certification to—

(A) The following certification criteria:

(*1*) CPOE at—

(*i*) 45 CFR 170.314(a)(1), (18), (19) or (20); or

(*ii*) 45 CFR 170.315(a)(1), (2) or (3).

(*2*)(*i*) Record demographics at 45 CFR 170.314(a)(3); or

(*ii*) 45 CFR 170.315(a)(5).

(*3*)(*i*) Problem list at 45 CFR 170.314(a)(5); or

(*ii*) 45 CFR 170.315(a)(6).

(*4*)(*i*) Medication list at 45 CFR 170.314(a)(6); or

(*ii*) 45 CFR 170.315(a)(7).

(*5*)(*i*) Medication allergy list 45 CFR 170.314(a)(7); or

(*ii*) 45 CFR 170.315(a)(8).

(*6*)(*i*) Clinical decision support at 45 CFR 170.314(a)(8); or

(*ii*) 45 CFR 170.315(a)(9).

(*7*) Health information exchange at transitions of care at one of the following:

(*i*) 45 CFR 170.314(b)(1) and (2).

(*ii*) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).

(*iii*) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).

(*iv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).

(*v*) 45 CFR 170.314(b)(8) and (h)(1).

(*vi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).

(*vii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).

(*viii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).

(*ix*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).

(*x*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).

(*xi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).

(*xii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).

(*xiii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).

(*xiv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).

(*xv*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).

(*xvi*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).

(*xvii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).

(*xviii*) 45 CFR 170.314(h)(1) and 170.315(b)(1).

(*xix*) 45 CFR 170.315(b)(1) and (h)(1).

(*xx*) 45 CFR 170.315(b)(1) and (h)(2).

(*xxi*) 45 CFR 170.315(b)(1), (h)(1), and (h)(2); and

(B) Clinical quality measures at—

(*1*) 45 CFR 170.314(c)(1) or 170.315(c)(1);

(*2*) 45 CFR 170.314(c)(2) or 170.315(c)(2);

(*3*) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (3) and optionally (4); or 45 CFR 170.315(c)(3)(i) and (ii) and optionally (c)(4); and can be electronically accepted by CMS if the provider is submitting electronically.

(C) Privacy and security at—

(*1*) 45 CFR 170.314(d)(1) or 170.315(d)(1);

(*2*) 45 CFR 170.314(d)(2) or 170.315(d)(2);

(*3*) 45 CFR 170.314(d)(3) or 170.315(d)(3);

(*4*) 45 CFR 170.314(d)(4) or 170.315(d)(4);

(*5*) 45 CFR 170.314(d)(5) or 170.315(d)(5);

(*6*) 45 CFR 170.314(d)(6) or 170.315(d)(6);

(*7*) 45 CFR 170.314(d)(7) or 170.315(d)(7);

(*8*) 45 CFR 170.314(d)(8) or 170.315(d)(8); and

(D) The certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS advancing care information performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(iii) The definition for 2018 and subsequent years specified in paragraph (2) of this definition.

(2) For 2018 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria—

(i) At 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to report on applicable objectives and measures specified for the MIPS advancing care information performance category including the following:

(A) The applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and optionally (c)(4), and can be electronically accepted by CMS.

Clinical Practice Improvement Activity (CPIA) means an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

CMS-approved survey vendor means a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and to transmit survey measures data to CMS.

CMS Web Interface means a web product developed by CMS that is used by groups that have elected to utilize the CMS Web Interface to submit data on the MIPS measures and activities.

Composite performance score (CPS) means a composite assessment (using a scoring scale of 0 to 100) for each MIPS eligible clinician for a specific performance period determined using the methodology for assessing the total performance for a MIPS eligible clinician according to performance standards for applicable measures and activities for each performance category. The CPS is the sum of each of the products of each performance category score and each performance category's assigned weight.

Covered professional services has the meaning given that term in section 1848(k)(3)(A) of the Act.

Eligible clinician has the meaning of the term "eligible professional" as defined in section 1848(k)(3) of the Act, is identified by a unique TIN and NPI combination and, means any of the following:

(1) A physician.

(2) A practitioner described in section 1842(b)(18)(C) of the Act.

(3) A physical or occupational therapist or a qualified speech-language pathologist.

(4) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Episode payment model means an APM or other payer arrangement that incentivizes improving the efficiency and quality of care for an episode of care by bundling payment for services furnished to an individual over a defined period of time for a specific clinical condition or conditions.

Estimated aggregate payment amounts means the total payments to a QP for Medicare Part B covered professional services for a year estimated by CMS as described in § 414.1450(b).

Group means a single TIN with two or more MIPS eligible clinicians, as identified by their individual NPI, who have reassigned their Medicare billing rights to the TIN.

Health professional shortage areas (HPSA) means areas as designated under section 332(a)(1)(A) of the Public Health Service Act.

High priority measure means an outcome, appropriate use, patient safety, efficiency, patient experience, or care coordination quality measure.

Hospital-based MIPS eligible clinician means a MIPS eligible clinician who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the performance period.

Incentive payment base period means the calendar year prior to the year in which CMS disburses the APM Incentive Payment. CMS uses estimated aggregate payments to a QP for Medicare Part B covered professional services during this period as the basis for determining the Estimated Aggregate Expenditures described in § 414.1450(b)(3).

Low-volume threshold means an individual MIPS eligible clinician or group who, during the performance period, have Medicare billing charges less than or equal to $10,000 and provides care for 100 or fewer Part B-enrolled Medicare beneficiaries.

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, and reports on applicable objectives and measures specified for the advancing care information performance category for a performance period in the form and manner specified by CMS.

Measure benchmark means the level of performance that the MIPS eligible clinician is assessed on for a specific performance period at the measures and activities level.

Medicaid APM means a payment arrangement authorized by a state Medicaid program that meets the criteria for an Other Payer Advanced APM under § 414.1420(a).

Medical Home Model means an APM under section 1115A of the Act that is determined by CMS to have the following characteristics:

(1) The APM's participants include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means involving specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Medicaid Medical Home Model means a payment arrangement under title XIX that CMS determines to have the following characteristics:

(1) The Other Payer APM's participants include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means involving specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant.;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned chronic and preventive care.

(ii) Patient access and continuity.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Merit-Based Incentive Payment System (MIPS) means the program required by section 1848(q) of the Act.

MIPS APM means an APM for which the APM scoring standard under § 414.1370 applies.

MIPS eligible clinician as identified by a unique TIN and NPI combination, means any of the following:

(1) A physician as defined in section 1861(r) of the Act.

(2) A physician assistant, a nurse practitioner, and clinical nurse specialist as such terms are defined in section 1861(aa)(5) of the Act.

(3) A certified registered nurse anesthetist as defined in section 1861(bb)(2) of the Act.

(4) A group that includes such clinicians.

MIPS payment year means the calendar year in which MIPS payment adjustments are applied.

New Medicare-Enrolled MIPS eligible clinician means an eligible clinician who first becomes a Medicare-enrolled eligible clinician within the Provider Enrollment, Chain and Ownership System (PECOS) during the performance period for a year and who had not previously submitted claims as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier.

Non-patient-facing MIPS eligible clinician means an individual MIPS eligible clinician or group that bills 25 or fewer patient-facing encounters during a performance period.

Other Payer Advanced APM means a payment arrangement that meets the criteria set forth in § 414.1420.

Partial Qualifying APM Participant (Partial QP) means an eligible clinician determined by CMS to have met the relevant Partial QP Threshold under § 414.1430(a)(2), (a)(4), (b)(2), and (b)(4) for a year.

Partial QP patient count threshold means the minimum threshold score in § 414.1430(a)(4) and (b)(4) an eligible clinician must attain through a patient count methodology described in §§ 414.1435(b) and 414.1440(c) to become a Partial QP for a year.

Partial QP payment amount threshold means the minimum threshold score in § 414.1430(a)(2) and (b)(2) an eligible clinician must attain through a payment amount methodology described §§ 414.1435(a) and 414.1440(b) to become a Partial QP for a year.

Participation List means the list of participants in an APM Entity that is compiled from a CMS-maintained list.

Performance category score means the assessment of each MIPS eligible clinician's performance on the applicable measures and activities for a performance category for a performance period based on the performance standards for those measures and activities.

Performance standards means the level of performance and methodology that the MIPS eligible clinician is assessed on for a MIPS performance period at the measures and activities level for all MIPS performance categories.

Performance threshold means the level of performance that is established for a performance period at the composite performance score level. CPSs above the performance threshold receive a positive MIPS adjustment factor and CPSs below the performance threshold receive a negative MIPS adjustment factor. CPSs that are equal to or greater than 0, but not greater than one-fourth of the performance threshold receive the maximum negative MIPS adjustment factor for the MIPS payment year. CPSs at the performance threshold receive a neutral MIPS adjustment factor.

Qualified Clinical Data Registry (QCDR) means a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Qualified registry means a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

QP patient count threshold means the minimum threshold score in § 414.1430(a)(3) and (b)(3) an eligible clinician must attain through a patient count methodology described in §§ 414.1435(b) and 414.1440(c) to become a QP for a year.

QP payment amount threshold means the minimum threshold score in § 414.1430(a)(1) and (b)(1) an eligible clinician must attain through the payment amount methodology described in §§ 414.1435(a) and 414.1440(b) to become a QP for a year.

QP Performance Period means the period of time that CMS will analyze to assess eligible clinician participation in Advanced APMs and Other Payer Advanced APMs for purposes of making the QP determinations in § 414.1425. The QP Performance Period is the calendar year that is two years prior to the payment year.

Qualifying APM Participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant payment amount or patient count QP threshold under § 414.1430(a)(1), (a)(3), (b)(1) or (b)(3) for a year based on participation in an Advanced APM Entity.

Rural areas means clinicians in counties designated as micropolitan or non-Core Based Statistical Areas (CBSAs), using HRSA's 2014–2015 Area Health Resource File (*http://datawarehouse.hrsa.gov/data/datadownload/ahrfdownload.aspx*).

Small practices means practices consisting of 15 or fewer clinicians.

Threshold Score means the percentage value that CMS determines for an eligible clinician based on the calculations described in §§ 414.1435 or 414.1440.

Topped out measure means a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors; or median value for a process measure that is 95 percent or greater.

§ 414.1310 Applicability.

(a) Except as specified in paragraph (b) of this section, MIPS applies to payments for items and services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) *Exclusions.* (1) For a year, a MIPS eligible clinician does not include an eligible clinician who:

(i) Is a Qualifying APM Participant as defined at § 414.1305;

(ii) Is a Partial Qualifying APM Participant (as defined at § 414.1305) for the most recent period for which data are available and who, for the performance period for the year, elects to not have measures and activities reported that are otherwise required to be reported by such professional under the MIPS; or

(iii) For the performance period with respect to a year, does not exceed the low-volume threshold as defined at § 414.1305.

(2) [Reserved]

(c) *Treatment of new Medicare-enrolled eligible clinicians.* New Medicare-enrolled eligible clinicians, as defined at § 414.1305, must not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year.

(d) In no case will a MIPS adjustment factor (or additional MIPS adjustment factor) apply to the items and services furnished by individuals who are not MIPS eligible clinicians, including the MIPS eligible clinicians described in paragraphs (b) and (c) of this section.

(e) *Requirements for groups.* (1) The following way is for individual MIPS eligible clinicians to have their performance assessed as a group:

(i) As part of a single TIN associated with two or more MIPS eligible clinicians, as identified by a NPI, that have their Medicare billing rights reassigned to the TIN.

(ii) [Reserved]

(2) A group must meet the definition of a group at all times during the performance period for the MIPS payment year in order to have its performance assessed as a group.

(3) Individuals MIPS eligible clinicians within a group must aggregate their performance data across the TIN.

(4) A group that elects to have its performance assessed as a group will be assessed as a group across all four MIPS performance categories.

(5) A group must adhere to an election process established and required by CMS.

§ 414.1315 [Reserved]

§ 414.1320 MIPS performance period.

For purposes of this subpart, the performance period for the year is the calendar year (January 1 through December 31) 2 years prior to the year in which the payment adjustment applies.

§ 414.1325 Data submission requirements.

(a) *Data submission performance categories.* MIPS eligible clinicians and groups must submit measures, objectives, and activities for the quality, CPIA, and advancing care information performance categories.

(b) *Data submission mechanisms for individual eligible clinicians.* An individual MIPS eligible clinician may elect to submit their MIPS data using:

(1) A qualified registry for the quality, CPIA, or advancing care information performance categories;

(2) The EHR submission mechanism (which includes submission of data by health IT vendors on behalf of MIPS eligible clinicians) for the quality, CPIA,

or advancing care information performance categories;

(3) A QCDR for the quality, CPIA, or advancing care information performance categories;

(4) Medicare Part B claims for the quality performance category; or

(5) Attestation for the CPIA and advancing care information performance categories.

(c) *Data submission mechanisms for groups that are not reporting through an APM.* Groups may submit their MIPS data using:

(1) A qualified registry for the quality, CPIA, or advancing care information performance categories;

(2) The EHR submission mechanism (which includes the submission of data by health IT vendors on behalf of groups) for the quality, CPIA, or advancing care information performance categories;

(3) A QCDR for the quality, CPIA, or advancing care information performance categories;

(4) A CMS Web Interface (for groups comprised of at least 25 MIPS eligible clinicians) for the quality, CPIA, and advancing care information performance categories;

(5) Attestation for the CPIA and advancing care information performance categories; or

(6) A CMS-approved survey vendor for groups that elect to include the CAHPS for MIPS survey as a quality measure. Groups that elect to include the CAHPS for MIPS survey as a quality measure must select one of the above data submission mechanisms to submit their other quality information.

(d) *Requirement to use only one submission mechanism per performance category.* Except as described in paragraph (c)(6) of this section, MIPS eligible clinicians and groups may elect to submit information via multiple mechanisms; however, they must use the same identifier for all performance categories and they may only use one submission mechanism per performance category.

(e) *Requirement to use a CMS-approved survey vendor to submit CAHPS data.* Groups that elect to include CAHPS for MIPS survey as a quality measure must use a CMS-approved survey vendor to submit CAHPS data but other quality data may be reported by any single one of the other available submission mechanisms for the quality performance category.

(f) *No data submission requirements for the resource use performance category and selected CPIA activities and quality measures.* There are no data submission requirements for the resource use performance category and for certain quality measures used to assess performance on the quality performance category and for certain activities in the CPIA performance category. CMS will calculate performance on these measures using administrative claims data.

(g) *Data submission deadlines for all submission mechanisms for individual eligible clinician and groups for all performance categories.* The submission deadlines are:

(1) For the qualified registry, QCDR, EHR, and attestation submission mechanisms shall be March 31 following the close of the performance period.

(2) For Medicare Part B claims, shall be on claims with dates of service during the performance period that must be processed no later than 90 days following the close of the performance period.

(3) For the CMS Web Interface, shall be an eight-week period following the close of the performance period. The period shall begin no earlier than January 1 and end no later than March 31.

§ 414.1330 Quality performance category.

(a) For purposes of assessing performance of MIPS eligible clinicians on the quality performance category, CMS will use:

(1) Quality measures included in the MIPS final list of quality measures.

(2) Quality measures used by QCDRs.

(b) Subject to CMS's authority to reweight performance category weights under section 1848(q)(5)(F) of the Act, performance in the quality performance category will comprise:

(1) 50 percent of a MIPS eligible clinician's composite performance score for 2019.

(2) 45 percent of a MIPS eligible clinician's composite performance score for 2020.

(3) 30 percent of a MIPS eligible clinician's composite performance score for each year thereafter.

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* A MIPS eligible clinician or group must submit data on MIPS quality measures in one of the following manners, as applicable:

(1) *Via claims, qualified registry, EHR or QCDR submission mechanism.* For the 12-month performance period—

(i) Submit data on at least six measures including one cross-cutting measure and at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures). If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(ii) Subject to paragraph (a)(1)(i) of this section, MIPS eligible clinicians and groups can either select their measures from the complete MIPS final measure list or a subset of that list, MIPS specialty-specific measure sets, as designated by CMS.

(2) *Via the CMS Web Interface—for groups only.* For the 12-month performance period—

(i) For a group of 25 or more MIPS eligible clinicians, report on all measures included in the CMS Web Interface. The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure/module.

(ii) If the sample of eligible assigned beneficiaries is less than 248, then the group must report on 100 percent of assigned beneficiaries. In some instances, the sampling methodology will not be able to assign at least 248 patients on which a group may report, particularly those groups on the smaller end of the range of 25–99 MIPS eligible clinicians.

(3) *Via CMS-approved survey vendor for CAHPS for MIPS survey—for groups only.* (i) For the 12-month performance period, a group who wishes to voluntarily elect to participate in the CAHPS for MIPS survey measures must use a survey vendor that is approved by CMS for a particular performance period to transmit survey measures data to CMS.

(A) The CAHPS for MIPS survey counts for one measure towards the MIPS quality performance category and also fulfills the requirement to report at least one cross-cutting measure (and in the absence of an applicable outcome measure, the requirement to report at least one high priority measure as a patient experience measure).

(B) Groups that elect this reporting mechanism must select an additional group data submission mechanism in order to meet the data submission criteria for the MIPS quality performance category.

(ii) [Reserved]

(b) *Exception.* MIPS eligible clinicians who are non-patient-facing eligible clinicians, as defined at § 414.1305, are not required to submit data on a cross-cutting measure.

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians and groups submitting quality measures data using the QCDR, qualified registry, or

EHR submission mechanism must submit data on at least 90 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer.

(b) MIPS eligible clinicians submitting quality measures data using Medicare Part B claims, must submit data on at least 80 percent of the applicable Medicare Part B patients.

(c) Groups submitting quality measures data using the CMS Web Interface or a CMS-approved survey vendor to submit the CAHPS for MIPS survey must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides.

§ 414.1350 Resource use performance category.

(a) For purposes of assessing performance of MIPS eligible clinicians on the resource use performance category, CMS specifies resource use measures for a performance period.

(b) Subject to CMS's authority to reweight performance category weights under section 1848(q)(5)(F) of the Act, performance in the resource use performance category comprises:

(1) 10 percent of a MIPS eligible clinician's composite performance score for MIPS payment year 2019.

(2) 15 percent of a MIPS eligible clinician's composite performance score for MIPS payment year 2020.

(3) 30 percent of a MIPS eligible clinician's composite performance score for each year thereafter.

§ 414.1355 Clinical practice improvement activity performance category.

(a) For purposes of assessing performance of MIPS eligible clinicians on the CPIA performance category, CMS specifies an inventory of measures and activities for a performance period.

(b) Subject to CMS's authority to reweight performance category weights under section 1848(q)(5)(F) of the Act, performance in the CPIA performance category comprises:

(1) 15 percent of an MIPS eligible clinician's composite performance score for MIPS payment year 2019 and for each year thereafter.

(2) [Reserved]

(c) The CPIA inventory shall include one or more of the following criteria (in any order):

(1) Relevant to an existing CPIA subcategory (or a proposed new subcategory).

(2) Importance of activity toward achieving improved beneficiary health outcome.

(3) Importance of activity that could lead to improvement in practice to reduce healthcare disparities.

(4) Aligned with patient-centered medical home.

(5) Representative of activities that multiple providers could perform (for example, primary care, specialty care).

(6) Feasible to implement, recognizing importance in minimizing provider burden, especially for small (consisting of 15 or fewer clinicians), practices located in rural areas, and geographic HPSAs designated by HRSA.

(7) CMS is able to be validate the activity; or

(8) Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes.

(d) For purposes of assessing performance of MIPS eligible clinicians on the CPIAs performance category, CMS uses activities included in the CPIA Inventory described in paragraph (c) of this section.

§ 414.1360 Data submission criteria for the clinical practice improvement activity performance category.

(a) MIPS eligible clinicians must submit data on MIPS CPIAs in one of the following manners:

(1) Via administrative claims (if technically feasible), qualified registry, EHR submission mechanisms, QCDR, CMS Web Interface or Attestation. For activities that are performed for at least 90-days during the performance period, MIPS eligible clinicians must—

(i) Submit a yes/no response for activities within the CPIA Inventory.

(ii) [Reserved]

(2) [Reserved]

(b) [Reserved]

§ 414.1365 Subcategories for the clinical practice improvement activity performance category.

(a) MIPS eligible clinicians select subcategories from the following:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other providers, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.

(5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an APM, as defined in section 1833(z)(3)(C) of the Act.

(7) Achieving health equity, as its own category or as a multiplier where the achievement of high quality in traditional areas is rewarded at a more favorable rate for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

(8) Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty military MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

(9) Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross-training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

(b) [Reserved]

§ 414.1370 APM scoring standard for MIPS.

(a) *General.* The APM scoring standard establishes a scoring methodology for APM Entity groups participating in MIPS APMs, defined at § 414.1305.

(b) *Criteria for the APM scoring standard under MIPS.* The APM scoring standard under MIPS applies to APM Entity groups participating in MIPS APMs, which are APMs that meet the following criteria:

(1) APM Entities participate in the APM under an agreement with CMS;

(2) The participating APM Entities include one or more MIPS eligible clinicians on a Participation List;

(3) The APM bases payment on cost/utilization and quality measures; and

(4) The APM does not have the following characteristics:

(i) *New APMs.* The APM scoring standard does not apply to an APM during a MIPS performance period if the APM's first performance year begins after the first day of that MIPS performance period.

(ii) *APMs for which using the APM scoring standard is impracticable.* If CMS determines within 60 days after the beginning of the MIPS performance period that it is impracticable for APM Entity groups to report to MIPS using the APM scoring standard in an APM's last year of operation, the APM scoring standard would not apply.

(c) *APM scoring standard performance period.* The MIPS performance period under § 414.1320 applies to the APM scoring standard.

(d) *APM participant identifier.* The APM participant identifier for an eligible clinician is the combination of four identifiers:

(1) APM identifier (established for the APM by CMS; for example, XXXXXX);

(2) APM Entity identifier (established for the APM by CMS; for example, AA00001111);

(3) Medicare-enrolled billing TIN (for example, XXXXXXXXX); and

(4) Eligible clinician NPI (for example, 1111111111).

(e) *APM Entity group.* (1) The APM Entity group consists of all eligible clinicians identified on the Participation List of the APM Entity on December 31 of the performance period.

(2) The APM scoring standard only applies to the eligible clinicians identified on the Participation List for an APM Entity group.

(3) CMS communicates to each APM Entity the list of eligible clinicians included in the APM Entity group as soon as practicable following the end of each calendar year.

(4) The MIPS composite performance score calculated for the APM Entity group is applied to each eligible clinician in the APM Entity group.

(5) The MIPS payment adjustment is applied at the TIN/NPI level for each of the eligible clinicians in the APM Entity group.

(f) *APM Entity group scoring under the APM scoring standard*—(1) *Quality.* (i) *APMs that submit quality data using the CMS Web Interface.* The MIPS performance category score for quality will be calculated for the APM Entity group using the data submitted for the APM Entity through the CMS Web Interface according to the terms of the APM.

(ii) *APMs that do not submit quality data using the CMS Web Interface.* For the MIPS 2019 payment year only, the quality performance category does not apply to MIPS eligible clinicians participating in MIPS APMs. This does not affect the requirements of an eligible clinician or APM Entity with regards to reporting and scoring under the APM. Starting in the MIPS 2020 payment year, the quality performance category will apply to MIPS eligible clinicians participating in MIPS APMs.

(2) *Resource use.* APM Entity groups are not assessed under the MIPS resource use performance category.

(3) *Clinical practice improvement activities.* (i) For APM Entity groups in the Shared Savings Program, each APM participant TIN submits data on the CPIA performance category according to the CPIA data submission criteria at § 414.1360 and have their performance on the CPIA performance category assessed as a group in accordance with § 414.1310(e). The APM Entity group CPIA performance category score is the weighted mean of the TIN group scores, weighted based on the number of MIPS eligible clinicians in the APM Entity that have reassigned their billing right to each respective TIN in the APM Entity.

(ii) For APM Entity groups in MIPS APMs other than the Shared Savings Program, each MIPS eligible clinician in the APM Entity submits data on the CPIA performance category according to the CPIA data submission criteria at § 414.1360. The MIPS eligible clinicians within the APM Entity will have their performance on the CPIA performance category assessed as individual MIPS eligible clinicians. The APM Entity group CPIA performance category score is the mean of the individual scores for each MIPS eligible clinician in the APM Entity group.

(4) *Advancing care information.* (i) For APM Entity groups in the Shared Savings Program, each APM participant TIN submits data on the advancing care information performance category according to the criteria at § 414.1375(b) and have their performance on the advancing care information performance category assessed as a group in accordance with § 414.1310(e). The APM Entity group advancing care information performance category score is the weighted mean of the TIN group scores, weighted based on the number of MIPS eligible clinicians in the APM Entity that have reassigned their billing right to each respective TIN in the APM Entity.

(ii) For APM Entity groups in MIPS APMs other than the Shared Savings Program, each MIPS eligible clinician in the APM Entity submits data on the advancing care information performance category according to the criteria at § 414.1375(b). The MIPS eligible clinicians within the APM Entity will have their performance on the advancing care information performance category assessed as individual MIPS eligible clinicians. The APM Entity group advancing care information performance category score is the mean of the individual scores for each eligible clinician in the APM Entity group.

(g) *APM Entity group performance category weights.* For the 2019 payment adjustment, the performance category weights for APM Entity groups are:

(1) *Quality.* (i) The Shared Savings Program and other MIPS APMs that submit quality data through the CMS Web Interface: 50 percent.

(ii) MIPS APMs that do not submit quality data through the CMS Web Interface: 0 percent.

(2) *Resource use:* 0 percent.

(3) *Clinical practice improvement activities.* (i) Shared Savings Program and other MIPS APMs that submit quality data through the CMS Web Interface: 20 percent.

(ii) MIPS APMs that do not submit quality data through the CMS Web Interface: 25 percent.

(4) *Advancing care information.* (i) Shared Savings Program and other APMs that submit quality data through the CMS Web Interface: 30 percent.

(ii) MIPS APMs that do not submit quality data through the CMS Web Interface: 75 percent.

§ 414.1375 Advancing care information performance category.

(a) *Composite performance score.* Subject to CMS's authority to reweight performance category weights under section 1848(q)(5)(E)(ii) and (q)(5)(F) of the Act, performance in the advancing care information performance category will comprise 25 percent of a MIPS eligible clinician's composite performance score for payment year 2019 and each year thereafter.

(b) *Reporting for the advancing care information performance category:* To earn a performance category score for the advancing care information performance category for inclusion in the composite performance score a MIPS eligible clinician must:

(1) Use CEHRT as defined at § 414.1305 for the MIPS performance period;

(2) *Report MIPS—advancing care information objectives and measures:* Report on the objectives and associated measures as defined for the performance period as follows:

(i) Report the numerator and denominator for all measures; or

(ii) Report the number and denominator for all applicable and available measures and a null value for any measure that:

(A) Is not applicable and available for the MIPS eligible clinician; and

(B) Includes a null value as an acceptable result in the measure specification.

(3) *Support information exchange and the prevention of health information blocking, and cooperate with authorized surveillance of CEHRT.* (i) The MIPS eligible clinician must attest to CMS that he or she cooperated in good faith with the surveillance and ONC direct review of his or her CEHRT under the ONC Health IT Certification Program, as authorized by 45 CFR part 170, subpart E, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by MIPS eligible clinician in the field.

(ii) *Support for health information exchange and the prevention of information blocking.* The MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT.

(B) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the CEHRT was, at all relevant times—

(*1*) Connected in accordance with applicable law;

(*2*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(*3*) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*4*) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate CEHRT and health IT vendors.

(c) *Good faith and timely responses.* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or health IT vendor.

§ 414.1380 Scoring.

(a) *General.* MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a Composite Performance Score (CPS), composed of their scores on individual measures and activities, and calculated according to the finalized CPS methodology.

(1) Measures and activities in the four performance categories are scored against performance standards.

(i) For the quality and resource use performance categories, measures are scored between zero and 10 points against performance standards that we refer to as measure benchmarks. Bonus points are available for the quality performance category for both reporting specific types of measures and using CEHRT systems to capture and report quality measures.

(ii) For the CPIA performance category, each CPIA is worth a certain number of points. The points for each reported activity is summed and compared against the highest potential score.

(iii) For the advancing care information performance category, performance is the sum of a base score and performance score.

(A) Base score: Achieved by meeting the Protect Patient Health Information measure and reporting the numerator (of at least one) and denominator or yes/no statement as appropriate (only a yes statement would qualify for credit under the base score) for each required measure.

(B) Performance score: Decile scale for additional achievement on selected measures above their base score requirement.

(2) MIPS eligible clinicians meeting applicable data completeness criteria receive credit for applicable measures and activities.

(3) All performance levels receive points provided that data meet the required case minimum, data completeness and sufficient benchmark for the quality and resource use performance categories.

(4) The baseline period is 2 years prior to the performance period for the MIPS payment year.

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories.

(1) *Quality performance category.* MIPS eligible clinicians receive one to ten achievement points for each scored quality measure in the quality performance category based on the MIPS eligible clinician's performance compared to applicable measure benchmarks. Each scored MIPS quality measure must have a measure benchmark. *Exception.* The maximum number of points for a topped out measure is the midpoint of the highest and lowest scores within a cluster.

(i) Measure benchmarks are based on historical performance for the measure based on a baseline period and each benchmark must have a minimum of 20 MIPS eligible clinicians who reported the measure meeting the data completeness requirement and minimum case size criteria.

(ii) *Exception.* If there is no comparable data from the baseline period, CMS would use information from the performance period to assess measure benchmarks and actual performance benchmarks would not be published until after the performance period.

(A) CMS Web Interface submission uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(B) [Reserved]

(iii) Separate benchmarks are used for the following submission mechanisms:

(A) EHR submission options;

(B) Administrative claims submission options;

(C) QCDR and qualified registry submission options;

(D) CMS Web Interface submission options;

(E) Claims submission options.

(iv) Minimum case requirements for quality measures are 20 cases, unless a measure is subject to an exception.

(v) *Exception.* The minimum case requirements for the all-cause readmission measure is 200 cases.

(vi) MIPS eligible clinicians failing to report a measure expected under this category receive zero points for that measure.

(vii) MIPS eligible clinicians do not receive zero points if the expected measure is submitted (meeting the data completeness criteria) but is unable to be scored because it does not meet the required case minimum or if the measure does not have a measure benchmark.

(viii) Measures that are not able to be scored would not be included for the MIPS quality performance category scoring.

(ix) MIPS eligible clinicians are scored using a percentile distribution, separated by decile categories.

(x) For each set of benchmarks, CMS calculates the decile breaks for measure performance and assigns points based on which benchmark decile range the MIPS eligible clinician's measure rate is between.

(xi) CMS assigns partial points based on the percentile distribution.

(xii) MIPS eligible clinicians are required to submit measures consistent with § 414.1335.

(xiii) Bonus points are available for measures determined to be high priority measures when two or more high priority measures are reported.

(A) Bonus points are not available for the first reported high priority measure which is required to be reported. To qualify for bonus points, each measure must be reported with sufficient case volume to meet the required case minimum and does not have a zero percent performance rate, regardless of whether it is included in the calculation of the quality performance category score.

(B) Outcome and patient experience measures receive two bonus points.

(C) Other high priority measures receive one bonus point.

(D) Bonus points for high priority measures cannot exceed 5 percent of the total possible points.

(xiv) Bonus points are also available for each measure submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary. Bonus points cannot exceed 5 percent of the total possible points.

(xv) A MIPS eligible clinician's quality performance score is the sum of all the points assigned for the measures required for the quality category criteria plus the bonus points in paragraph (b)(1)(xiii) and bonus points in paragraph (b)(1)(xiv) of this section. The sum is divided by the sum of total possible points.

(2) *Resource use performance category.* MIPS eligible clinicians receive one to ten achievement points for each measure in the resource use performance category based on the MIPS eligible clinician's performance compared to applicable benchmarks.

(i) Each MIPS resource use measure has a measure benchmark that is based on the performance period.

(ii) Only measures meeting the required case minimum are scored under this category. Minimum case requirements for resource use measures are 20 cases.

(iii) A MIPS eligible clinician's resource use performance category score is the equally-weighted average of all scored measures.

(3) *Clinical practice improvement activities (CPIA) performance category.* MIPS eligible clinicians and groups receive points for CPIA based on patient-centered medical home or comparable specialty practice participation, APM participation, and CPIA reported by the MIPS eligible clinician in comparison to the highest potential score (60 points) for a given MIPS year.

(i) CMS assigns points for each reported CPIA within two weights: Medium-weighted; and high-weighted activities.

(ii) CPIA with high weighting receive 20 points.

(iii) CPIA with medium weighting receive 10 points.

(iv) MIPS eligible clinician or group in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, receives full credit for CPIA performance. For purposes of this paragraph (b)(3)(iv), "full credit" means that the MIPS eligible clinician or group has met the highest potential score. A practice is certified as a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from one of four accreditation organizations that are nationally recognized;

(*1*) The Accreditation Association for Ambulatory Health Care;

(*2*) The National Committee for Quality Assurance (NCQA);

(*3*) The Joint Commission; or

(*4*) The Utilization Review Accreditation Commission (URAC).

(B) The practice is a Medicaid Medical Home or Medical Home Model.

(C) The practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition.

(v) CMS compares the points associated with the reported activities against the CPIA highest potential score (60 points).

(vi) A MIPS eligible clinician or group's CPIA category score is the sum of points for all of their reported activities divided by the CPIA highest potential score of 60 points.

(vii) Non-patient-facing MIPS eligible clinicians and groups, small practices (consisting of 15 or fewer professionals), and practices located in rural areas and geographic HPSAs receive credit for CPIA by selecting one or two of any type of CPIA weighted activity.

(A) For purposes of this paragraph (b)(3)(vii), "credit" is considered 50 percent of the total of 60 points for one activity of any weight, and 100 percent of the total of 60 points for two activities of any weight.

(B) [Reserved]

(4) *Advancing care information performance category.* (i) For the advancing care information performance category, MIPS eligible clinicians receive an overall performance category score equal to the sum of the base score, performance score and optional Public Health and Clinical Data Registry bonus point. The total score shall not exceed 100 percent.

(A) MIPS eligible clinicians earn a base score by reporting the numerator (of at least one)/denominator or yes/no statement as applicable (only a yes statement would qualify for credit under the base score) in the objectives and measures.

(B) MIPS eligible clinicians earn percentage points towards the performance score by reporting on the eight associated measures under the Patient Electronic Access, Coordination of Care through Patient Engagement, and Health Information Exchange objectives.

(C) MIPS eligible clinicians earn one additional bonus point for reporting any additional measures above the base score requirement for the Public Health and Clinical Data Registry objective.

(ii) [Reserved]

(c) *Composite performance score (CPS) calculation.* MIPS eligible clinicians receive a CPS of 0 to 100 points based on the sum of the products of each performance category's score and its assigned weight, multiplied by 100.

(1) *Performance category weights.* The following are the performance category weights subject to CMS's authority to reweight the measure categories under section 1848(q)(5)(F) of the Act are defined as follows.

(i) Quality performance category weight is defined under § 414.1330(b).

(ii) Resource use performance category weight is defined under § 414.1350(b).

(iii) CPIA performance category weight is defined under § 414.1355(b).

(iv) Advancing care information performance category weight: 25 Percent for the 2019 MIPS payment year.

(2) *Calculating the CPS.* (i) CMS applies category weights to each performance category score.

(ii) CMS calculates the CPS according to its finalized formulas.

(3) CMS reweights the performance category scores for MIPS eligible clinicians when they do not have sufficient applicable or available measures using the authority under section 1848(q)(5)(F) of the Act.

(4) The CPS forms the basis for payment adjustments under this section. The CPS must be based on a minimum of two scored performance categories. If a MIPS eligible clinician only has one scored performance category, the MIPS eligible clinician is assigned a CPS that is equal to the performance threshold and the MIPS eligible clinician receives a MIPS adjustment factor of 0 percent for the year.

(e) *Scoring for APM entities.* MIPS eligible clinician in APM entities that are subject to the APM scoring standard are scored using the method under § 414.1370.

§ 414.1385 Targeted review and review limitations.

(a) *Targeted review.* MIPS eligible clinicians or groups may request a targeted review of the calculation of the MIPS adjustment factor under section 1848(q)(6)(A) of the Act, and, as applicable the calculation of the additional MIPS adjustment factor under section 1848(q)(6)(C) of the Act to such MIPS eligible clinician for a performance year. This review will be limited to the calculation of the MIPS adjustment factor and, as applicable, the additional MIPS adjustment factor for which we may find it necessary to review data related to measures and activities and the calculation of the CPS according to the defined methodology. The process for targeted reviews is:

(1) A MIPS eligible clinician may submit their election to request a targeted review to CMS within 60 days (or a longer period specified by CMS) after the close of the data submission period. All requests for targeted review must be submitted by July 31 after the close of the data submission period or by a later date that we specify.

(2) A response on whether or not a targeted review is warranted will be provided by CMS.

(3) There will not be a hearing or evidence submission process, although the MIPS eligible clinician may submit information to assist in the review.

(4) All decisions based on the targeted review will be final.

(5) There will be no further review or appeal.

(b) *Limitations on review.* Except as specified in paragraph (a)(4) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The methodology used to determine the amount of the MIPS adjustment factor and the amount of the additional MIPS adjustment factor and the determination of such amounts;

(2) The establishment of the performance standards and the performance period;

(3) The identification of measures and activities specified for a MIPS performance category and information made public or posted on a CMS public Web site; and

(4) The methodology developed that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

§ 414.1390 Data validation and auditing.

(a) *General.* CMS will selectively audit MIPS eligible clinicians on a yearly basis. If a MIPS eligible clinician or group is selected for audit, the MIPS eligible clinician or group is be required to do the following in accordance with applicable law:

(1) Comply with data sharing requests, providing all data as requested by us or our designated entity. All data must be shared with CMS or our designated entity within 10 business days or an alternate time frame that is agreed to by CMS and the MIPS eligible clinician or group. Data will be submitted via email, facsimile, or an electronic method via a secure Web site maintained by CMS.

(2) Provide substantive, primary source documents as requested. These documents may include: Copies of claims, medical records for applicable patients, or other resources used in the data calculations for MIPS measures, objectives, and activities. Primary source documentation also may include verification of records for Medicare and non-Medicare beneficiaries where applicable.

(b) [Reserved]

§ 414.1395 Public reporting.

(a) *Public reporting of an MIPS eligible clinician's MIPS data.* For each program year, CMS would post on a public Web site, in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under the MIPS.

(b) [Reserved]

§ 414.1400 Third party data submission.

(a) *General.* (1) MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by:

(i) A qualified registry;

(ii) A QCDR;

(iii) A health IT vendor that obtains data from a MIPS eligible clinician's CEHRT; or

(iv) A CMS-approved survey vendor.

(2) Qualified registries, QCDRs, and health IT vendors may submit data on measures, activities, or objectives for any of the following MIPS performance categories:

(i) Quality;

(ii) CPIA; or

(iii) Advancing care information, if the MIPS eligible clinician or group is using CEHRT.

(3) CMS-approved survey vendors may submit data for the CAHPS for MIPS survey under the MIPS quality performance category.

(4) Third party intermediaries must meet all the requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary, including the following requirements:

(i) For measures, activities, and objectives under the quality, advancing care information, and CPIA performance categories, if the data is derived from CEHRT, the QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(ii) All submitted data must be submitted in the form and manner specified by CMS.

(b) *QCDR self-nomination requirements.* QCDRs must self-nominate, for the 2017 performance period, from November 15, 2016 until January 15, 2017. For future years of the program, starting with the 2018 performance period, QCDRs must self-nominate from September 1 of the prior year until November 1 of the prior year. Entities that desire to qualify as a QCDR for the purposes of MIPS for a given performance period will need to self-nominate for that year and provide all information requested by CMS at the time of self-nomination. Having qualified as a QCDR does not automatically qualify the entity to participate in subsequent MIPS performance periods.

(c) *Establishment of a QCDR entity.* For an entity to become qualified for a given performance period as a QCDR, the entity must:

(1) Be in existence as of January 1 of the performance period for which the entity seeks to become a QCDR.

(2) Have at least 25 participants by January 1 of the performance period.

(d) *Collaboration of entities to become a QCDR.* In situations where an entity may not meet the requirements of a QCDR solely on its own but can do so in conjunction with another entity, the entity must also comply with the following:

(1) An entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR.

(2) Entities with a mere verbal, non-written agreement to work together to become a QCDR by September 1 of the year prior to the year for which the entity seeks to become a QCDR would not fulfill this requirement.

(e) *Identifying non-MIPS quality measures.* For purposes of QCDRs submitting data for the MIPS quality performance category, CMS considers the following types of quality measures to be non-MIPS quality measures:

(1) A measure that is not contained in the annual list of MIPS quality measures for the applicable performance period.

(2) A measure that may be in the annual list of MIPS quality measures but has substantive differences, as determined by the Secretary, in the manner it is reported by the QCDR.

(3) CAHPS for MIPS survey.

(f) *QCDR measure specifications requirements.* A QCDR must provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS. The QCDR must provide CMS descriptions and narrative specifications for each measure, activity, or objective no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data. In future years, starting with the 2018 performance period, those specifications must be provided to CMS by no later than November 1 prior to the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data.

(1) For non-MIPS quality measures, the quality measure specifications must include the following for each measure: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. The narrative specifications provided must be similar to the narrative specifications we provide in our measures list. CMS will consider all non-MIPS quality measures submitted by the QCDR but the measures must address a gap in care and outcome or other high priority measures are preferred. Documentation or "check box" measures are discouraged. Measures that have very high performance rates already or address extremely rare gaps in care (thereby allowing for little or no quality distinction between eligible clinicians) are also unlikely to be approved for inclusion.

(2) For MIPS quality measures, the QCDR only needs to submit the MIPS measure numbers and/or specialty-specific measure sets (if applicable).

(3) The QCDR must publicly post the measure specifications (no later than 15 days following CMS approval of the measure specifications) for each non-MIPS quality measure it intends to submit for MIPS. The QCDR may use any public format it prefers. Immediately following posting of the measures specification, the QCDR must provide CMS with the link to where this information is posted.

(g) *Qualified registry self-nomination requirements.* Qualified registries must self-nominate, for the 2017 performance period from November 15, 2016 until January 15, 2017. For future years of the program, starting with the 2018 performance period, the qualified registry must self-nominate from September 1 of the prior year until November 1 of the prior year and provide all requested information to CMS at the time of self-nomination. Entities that desire to be a qualified registry for a given performance period will need to self-nominate for that performance period. Having qualified as a qualified registry does not automatically qualify the entity to participate in subsequent MIPS performance periods.

(h) *Establishment of a qualified registry entity.* In order for an entity to become qualified for a given performance period as a qualified registry, the entity must:

(1) Be in existence as of January 1 the performance period for which the entity seeks to become a qualified registry.

(2) Have at least 25 participants by January 1 of the performance period.

(i) *CMS-approved survey vendor application requirements.* Vendors are required to undergo the CMS approval process for each year in which the survey vendor seeks to transmit survey measures data to CMS. All CMS-approved survey vendor applications and materials will be due by April 30 of the performance period.

(j) *Auditing of entities submitting MIPS data.* Any third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) must comply with the following requirements as a condition of their qualification or approval to participate in MIPS as a third party intermediary.

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information will include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email.

(2) The entity must retain all data submitted to CMS for MIPS for a minimum of 10 years.

(k) *Probation and disqualification of a third party intermediary.* (1) If at any time we determine that a third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) has not met all of the applicable requirements for qualification, CMS may place the third party intermediary on probation for the current performance period and/or the following performance period, as applicable.

(2) CMS requires a corrective action plan from the third party intermediary to address any deficiencies or issues and prevent them from recurring. The corrective action plan must be received and accepted by CMS within 14 days of the CMS notification to the third party intermediary of the deficiency or probation. Failure to comply with this requirement will lead to disqualification from the MIPS program for the subsequent performance period.

(3) Probation means that, for the applicable performance period, the third party intermediary is not allowed to miss any meetings or deadlines and will need to submit a corrective action plan for remediation or correction of any deficiencies identified by CMS that resulted in the probation.

(4) If the third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, CMS will annotate on the CMS qualified posting that the entity furnished data of poor quality and will place the third party intermediary on probation for the subsequent MIPS performance period with the opportunity to go on probation for a year to correct deficiencies.

(5) If the third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary will continue to be on probation and have their listing on the CMS Web site continue to note the poor quality of the data they are submitting for MIPS for one additional year. After two years on probation, the third party intermediary will be disqualified for the subsequent performance period.

(6) In placing the third party intermediary on probation; CMS would notify the third party intermediary of the identified issues, at the time of discovery of such issues.

(7) Data errors affecting in excess of 5 percent of the MIPS eligible clinicians or groups submitted by the third party intermediary may lead to the disqualification of the third party intermediary from participation in MIPS for the following performance period.

(8) If the third party intermediary does not submit an acceptable corrective

action plan within 14 days of notification of deficiencies, and correct the deficiencies within 30 days or before the submission deadline—whichever is sooner, CMS may disqualify the third party intermediary from participating in MIPS for the current performance period and/or the following performance period, as applicable.

§ 414.1405 Payment.

(a) *General.* MIPS eligible clinicians receive payment adjustments based on their composite performance scores (CPS).

(b) *Performance threshold.* The performance threshold for the 2019 MIPS payment year is set at a level where approximately half of MIPS eligible clinicians fall below the threshold and approximately half are above it, as estimated by the Secretary.

(c) *Applicable percentage.* Applicable percentage for MIPS payment year 2019 is 4 percent.

(d) *Linear sliding scale.* The CPS is measured on a linear sliding scale between the negative applicable percentage and positive applicable percentage.

(1) *Exception.* MIPS eligible clinicians with a CPS that fall between zero points and one-quarter of the performance threshold receive the negative applicable percentage.

(2) MIPS eligible clinicians with a positive adjustment receive a payment against the applicable percentage and a scaling factor not to exceed 3.0.

(e) *Additional performance threshold.* MIPS eligible clinicians with a CPS at least equal to the 25th percentile of the range of possible scores above the performance threshold, or the 25th percentile of the actual CPS at or above the performance threshold for the prior period used to determine the performance threshold, receive an additional positive adjustment factor for exceptional performance.

(f) *Linear sliding scale for additional payment adjustment.* The CPS is measured on a linear sliding scale between 0.5 percent at the additional performance threshold and 10 percent at a CPS of 100. If necessary, the scale is adjusted downward by applying a scaling factor between 0 and 1 so that total dispersed payments are not expected to exceed $500,000,000 and the maximum payment adjustment would not exceed 10 percent.

§ 414.1410 Advanced APM determination.

(a) *General.* An Alternative Payment Model (APM) is an Advanced APM for a payment year if CMS determines that it meets the criteria in § 414.1415 during the QP Performance Period.

(b) *Advanced APM determination process.* (1) CMS identifies Advanced APMs and Other Payer Advanced APMs in the following manner:

(i) *Advanced APM determination.* (A) No later than January 1, 2017, CMS will post on its Web site a list of all Advanced APMs for the first QP Performance Period.

(B) CMS updates the Advanced APM list on its Web site at intervals no less than annually.

(ii) Notwithstanding paragraph (b)(2) of this section, CMS includes notice of whether a new APM is an Advanced APM in the first public notice of the new APM.

(2) *Other Payer Advanced APM determination process.* (i) CMS identifies Other Payer Advanced APMs following the QP performance period using information submitted to CMS according to § 414.1445. CMS will not make determinations for other payer arrangements for which insufficient information is submitted.

(ii) CMS makes early Other Payer Advanced APM determinations prior to QP determinations under § 414.1440.

(iii) CMS makes final Other Payer Advanced APM determinations and notifies Advanced APM Entities and eligible clinicians of such determinations as soon as practicable.

§ 414.1415 Advanced APM criteria.

(a) *Use of certified electronic health record technology.* The following constitutes use of CEHRT:

(1) *Definition of certified EHR technology (CEHRT).* For the purposes of the Advanced APM criteria, CMS uses the definition of CEHRT provided in the EHR performance category in MIPS and defined at § 414.1305.

(2) *Required use of certified EHR technology.* To be an Advanced APM, an APM must:

(i) Require at least 50 percent of eligible clinicians in each participating APM Entity group, or each hospital if hospitals are the APM Entities, to use CEHRT to document and/or communicate clinical care to their patients or other health care providers.

(ii) For the Shared Savings Program, apply a penalty, reward, and/or similar financial component to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity.

(b) *Payment based on quality measures.* (1) To be an Advanced APM, an APM must include quality measure results as a factor in determining payment to APM Entities.

(2) At least one of the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(i) Used in the MIPS quality performance category, as described in § 414.1330.

(ii) Endorsed by a consensus-based entity;

(iii) Developed under section 1848(s) of the Act;

(iv) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(v) Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

(3) In addition to the quality measure requirements under paragraph (b)(2) of this section, the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one outcome measure. This requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the Advanced APM's first QP Performance Period.

(c) *Financial risk.* To be an Advanced APM, an APM must either meet both the financial risk standard and nominal risk standard described in paragraphs (c)(1) and (c)(2) of this section or be an expanded Medical Home Model as described in paragraph (c)(5) of this section.

(1) *Financial risk standard.* Except for paragraph (c)(1)(ii) of this section, to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified performance period do one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iii) Require the APM Entity to owe payment(s) to CMS.

(2) *Medical home financial risk standard.* For an APM Entity owned and operated by an organization with fewer than 50 Clinicians whose Medicare billing rights have been reassigned to the TIN of the organization or any of the organization's subsidiary entities, the following standard applies instead of the standard set forth in paragraph (c)(1)(i) of this section. An APM Entity participates in a Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

(i) Withholds payment for services to the APM Entity or the APM Entity's eligible clinicians.

(ii) Reduces payment rates to the APM Entity or the APM Entity's eligible clinicians.

(iii) Requires the APM Entity to owe payment(s) to CMS.

(iv) Causes the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

(3) *Nominal amount standard.* (i) Except for risk arrangements described under paragraph (c)(3)(ii) of this section, the risk arrangement must have:

(A) A marginal risk rate of at least 30 percent; and

(B) Total potential risk of at least four percent of the expected expenditures.

(ii) *Medical home model nominal amount standard.* For an APM Entity owned and operated by an organization with fewer than 50 eligible clinicians whose Medicare billing rights have been reassigned to the TIN of the organization or any of the organization's subsidiary entities, the following standard applies instead of the standard set forth in this paragraph (c)(3)(ii). For a Medical Home Model to be an Advanced APM, the minimum total annual amount that an APM Entity must potentially owe or forego under the APM must be:

(A) In 2017, 2.5 percent of the APM Entity's total Medicare Parts A and B revenue;

(B) In 2018, 3 percent of the APM Entity's total Medicare Parts A and B revenue.

(C) In 2019, 4 percent of the APM Entity's total Medicare Parts A and B revenue.

(D) In 2020 and later, 5 percent of the APM Entity's total Medicare Parts A and B revenue.

(4) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the ratio of financial risk to the amount that actual expenditures exceed expected expenditures.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the lowest marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (c)(3)(i)(A) of this section, with exceptions for large losses as described in paragraph (c)(4)(ii) of this section and small losses as described in paragraph (c)(4)(iii) of this section.

(ii) Allowance for large losses. The determination in paragraph (c)(4)(i) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments to CMS greater than or equal to the total risk requirement under paragraph (c)(3)(i)(B) of this section.

(iii) Allowance for minimum loss rate. The determination in paragraph (c)(4)(i) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(5) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the APM benchmark, except for episode payment models, for which it is defined as the episode target price.

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this subpart, a capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made to an APM Entity for all items and services furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements made between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. section 422) are not considered capitation arrangements for purposes of this paragraph (c)(6).

(7) *Medical Home Model Expanded under section 1115A(c) of the Act.* A Medical Home Model that has been expanded under section 1115A(c) of the Act meets the financial risk criterion under this section.

§ 414.1420 Other payer advanced APMs.

(a) *Other Payer Advanced APM criteria.* A payment arrangement with a payer other than CMS is an Other Payer Advanced APM for a QP Performance Period if CMS determines that the arrangement meets the following criteria during the QP Performance Period:

(1) Use of CEHRT, as described in paragraph (b) of this section;

(2) Quality measures comparable to measures under the MIPS quality performance category apply, as described in paragraph (c) of this section; and

(3) Either:

(i) Requires APM Entities to bears more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures, as described in paragraph (d) of this section; or

(ii) Is a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act, as described in paragraph (d)(3) of this section.

(b) *Use of certified EHR technology (CEHRT).* To be an Other Payer Advanced APM, another payer arrangement must require participants to use the CEHRT defined in paragraph (b)(1) of this section in the manner described in paragraph (b)(2) of this section.

(1) *For purposes of this Advanced APM criterion, CEHRT is defined* at § 414.1305.

(2) *Required use of certified EHR technology.* To be an Other Payer Advanced APM, an APM must require at least 75 percent of eligible clinicians in each participating APM Entity group, or each hospital if hospitals are the APM Entities, to use CEHRT to document and/or communicate clinical care to their patients or other health care providers.

(c) *Other Payer Advanced APM quality measures.* (1) To be an Other Payer Advanced APM, an Other Payer APM must apply quality measures comparable to measures under the MIPS quality performance category, as described in paragraph (c)(2) of this section.

(2) At least one of the quality measures used in the arrangement with an APM Entity must have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(i) Used in the MIPS quality performance category, as described in § 414.1330;

(ii) Endorsed by a consensus-based entity;

(iii) Developed under section 1848(s) of the Act;

(iv) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(v) Any other quality measures that CMS determines to have an evidence-based focus and are reliable and valid.

(3) To meet the quality measure criterion, an Other Payer Advanced APM must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. If an Other Payer Advanced APM has no outcome measure, the Advanced APM Entity must attest that there is no applicable outcome measure on the MIPS list.

(d) *Other Payer Advanced APM financial risk.* To be an Other Payer Advanced APM, an Other Payer APM must meet either the criterion described in paragraph (d)(1) of this section or the criterion described in § 414.1420(d)(3).

(1) *Other Payer Advanced APM financial risk standard.* Except for APM Entities to which paragraph (d)(2) of this

section applies, to be an Other Payer Advanced APM an Other Payer APM must, if APM Entity actual aggregate expenditures exceed expected aggregate expenditures during a specified performance period:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iii) Require direct payment by the APM Entity to the payer.

(2) *Medicaid medical home financial risk standard.* For an APM Entity owned and operated by an organization with fewer than 50 eligible clinicians whose Medicare billing rights have been reassigned to the TIN of the organization or any of the organization's subsidiary entities, the following standard applies instead of the standard set forth in paragraph (c)(1)(i) of this section. The Advanced APM Entity participates in a Medicaid Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Require direct payment by the APM Entity to the payer;

(iii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians, or

(iv) Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

(3) *Other Payer Advanced APM nominal amount standard.* (i) Except for risk arrangements described under paragraph (d)(2) of this section, the risk arrangement must have:

(A) A marginal risk rate of at least 30 percent; and

(B) Total potential risk of at least four percent of expected expenditures.

(ii) *Medicaid Medical Home Model nominal amount standard.* For an APM Entity owned and operated by an organization with fewer than 50 eligible clinicians whose Medicare billing rights have been reassigned to the TIN of the organization or any of the organizations subsidiary entities, the following standard applies instead of the standard set forth in paragraph (d)(1) of this section. For Medicaid Medical Home Models, the minimum total annual amount that an APM Entity must potentially owe or forego under the APM must be:

(A) In 2019, 4 percent of the APM Entity's total Medicare Parts A and B revenue.

(B) In 2020 and later, 5 percent of the APM Entity's total Medicare Parts A and B revenue.

(4) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the ratio of financial risk to the amount that actual expenditures exceed expected expenditures.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the lowest marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(i)(A) of this section, with exceptions for large losses as described in paragraph (d)(4)(ii) of this section and small losses as described in paragraph (d)(4)(iii) of this section.

(ii) Allowance for large losses. The determination in paragraph (d)(4)(i) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the Other Payer Advanced APM greater than or equal to the total risk requirement under paragraph (d)(3)(i)(B) of this section.

(iii) Allowance for minimum loss rate. The determination in paragraph (d)(4)(i) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(5) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the Other Payer APM benchmark, except for episode payment models, for which it is defined as the episode target price.

(6) *Capitation.* A capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made to an APM Entity for services furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (d)(6).

(7) *Comparability to expanded Medical Home Model.* (i) The financial risk criterion under § 414.1420(d) is met for a Medicaid Medical Home Model if CMS determines that it has characteristics that are comparable to any Medical Home Model expanded under section 1115A(c) of the Act.

(ii) For each Medical Home Model that is expanded under section 1115A(c) of the Act, CMS will publish the characteristics of such models against which Medicaid Medical Home Models will be compared under paragraph (a) of this section through notice and comment rulemaking.

§ 414.1425 Qualifying APM participant determination: In general.

(a) *QP Performance Period.* The QP Performance Period for a payment year is the period of time during which CMS assesses claims to make a QP determination under this § 414.1425. The QP Performance Period for a payment year is the calendar year that ends 1 year and 1 day before the payment year.

(b) *Advanced APM Entity group determination.* Except for § 414.1445, for purposes of determining QPs for a year, eligible clinicians are grouped and assessed through their collective participation in an Advanced APM Entity, as described in § 414.1305. To be included in the eligible clinician group defined by an Advanced APM Entity for purposes of the QP determination, an eligible clinician's APM participant identifier must be present on a Participation List on December 31 of the QP Performance Period:

(1) *Participation List.* For Advanced APMs that include a Participation List that can be used to identify eligible clinicians, the Participation List will be the APM Entity group for the QP determination.

(2) *Affiliated Practitioner List.* For Advanced APMs that do not include a Participation List that can be used to identify eligible clinicians and do include an Affiliated Practitioner List, the Affiliated Practitioner List will be the APM Entity group for the QP determination.

(c) *QP determination.* (1) CMS makes QP determinations in accordance with the methods set forth in §§ 414.1435 and 414.1440.

(2) An eligible clinician cannot be both a QP and a Partial QP for a year. A determination that an eligible clinician is a QP means that the eligible clinician is not a Partial QP.

(3) An eligible clinician is a QP for a year if the eligible clinicians that constitute the group for the QP Determination under paragraph (b) of this section for an Advanced APM Entity collectively achieve a Threshold Score that meets or exceeds the corresponding QP threshold for that

year, as described in § 414.1430(a)(1), (3), (b)(1) and (3).

(4) Notwithstanding paragraph (c)(3) of this section, an eligible clinician is a QP for a year if:

(i) The eligible clinician is grouped with eligible clinicians for the QP Determination pursuant to paragraph (b) of this section for more than one Advanced APM Entity;

(ii) None of the eligible clinician's Advanced APM Entity eligible clinician groups meets the QP threshold; and

(iii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the corresponding QP threshold.

(5) An eligible clinician is a Partial QP for a year if the eligible clinician group used for the QP Determination pursuant to paragraph (b) of this section collectively achieves a Threshold Score that meets or exceeds the corresponding Partial QP threshold for that year, as described in § 414.1430(a)(2), (4), (b)(2), and (4).

(6) Notwithstanding paragraph (c)(5) of this section, an eligible clinician is a Partial QP for a year if:

(i) The eligible clinician is grouped with eligible clinicians for the QP Determination pursuant to § 414.1425(b) for more than one Advanced APM Entity;

(ii) None of the eligible clinician's Advanced APM Entity eligible clinician groups meets the QP or Partial QP threshold; and

(iii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the corresponding Partial QP threshold.

(d) *Notification of QP determination.* CMS notifies eligible clinicians determined to be QPs or Partial QPs for a year as soon as practicable following the end of the QP Performance Period. CMS may inform all eligible clinicians determined to be QPs collectively through their APM Entity determined to be an Advanced APM Entity.

(e) *Order of threshold options.* (1) For payment years 2019 and 2020, CMS performs QP determinations for an eligible clinicians only under the Medicare Option described in § 414.1435.

(2) For payment years 2021 and later, CMS performs QP determinations for eligible clinicians under the Medicare Option, as described in § 414.1435 and, except for (i) and (ii), the All-Payer Combination Option, described in § 414.1440.

(i) If CMS determines the eligible clinician or group of eligible clinicians to be a QP under the Medicare Option, then CMS does not perform a QP determination for such eligible clinician(s) under the All-Payer Combination Option.

(ii) If the Threshold Score for an eligible clinician or eligible clinician group under the Medicare Option is less than the amount in § 414.1430(b)(2)(ii) and (b)(3)(iii), then CMS does not perform a QP determination for such eligible clinician(s) under the All-Payer Combination Option.

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) *Medicare Option*—(1) *QP payment amount threshold.* The QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 25 percent.

(ii) 2021 and 2022: 50 percent.

(iii) 2023 and later: 75 percent.

(2) *Partial QP payment amount threshold.* The Partial QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent.

(ii) 2021 and 2022: 40 percent.

(ii) 2023 and later: 50 percent.

(3) *QP patient count threshold.* The QP patient count thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent.

(ii) 2021 and 2022: 35 percent.

(ii) 2023 and later: 50 percent.

(4) *Partial QP patient count threshold.* The Partial QP patient count thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 10 percent.

(ii) 2021 and 2022: 25 percent.

(iii) 2023 and later: 35 percent.

(b) *All-Payer Combination Option*—(1) *QP payment amount threshold.* (i) The QP payment amount thresholds are the following values for the indicated payment years:

(A) 2021 and 2022: 50 percent.

(B) 2023 and later: 75 percent.

(ii) To meet the QP payment amount threshold under this option, the eligible clinician group or eligible clinician must also meet a 25 percent QP payment amount threshold under the Medicare Option.

(2) *Partial QP payment amount threshold.* (i) The Partial QP payment amount thresholds are the following values for the indicated payment years:

(A) 2021 and 2022: 40 percent.

(B) 2023 and later: 50 percent.

(ii) To meet the QP payment amount threshold under this option, the eligible clinician group or eligible clinician must also meet a 20 percent Partial QP payment amount threshold under the Medicare Option.

(3) *QP patient count threshold.* (i) The QP patient count thresholds are the following values for the indicated payment years:

(A) 2021 and 2022: 35 percent.

(B) 2023 and later: 50 percent.

(ii) To meet the QP patient count threshold under this option, the eligible clinician group or eligible clinician must also meet a 20 percent QP patient count threshold under the Medicare Option.

(4) *Partial QP patient count threshold.* (i) The Partial QP patient count thresholds are the following values for the indicated payment years:

(A) 2021 and 2022: 25 percent.

(B) 2023 and later: 35 percent.

(ii) To meet the Partial QP patient count threshold under this option, the eligible clinician group or eligible clinician must also meet a 10 percent QP patient count threshold under the Medicare Option.

§ 414.1435 Qualifying APM participant determination: Medicare option.

(a) *Payment amount method.* The Threshold Score for an eligible clinician group or eligible clinician is calculated as a percent by dividing the value described under paragraph (a)(1) of this section by the value described under paragraph (a)(2) of this section.

(1) *Numerator.* The aggregate of all payments for Medicare Part B covered professional services furnished by the APM Entity group or eligible clinician to attributed beneficiaries during the QP Performance Period.

(2) *Denominator.* The aggregate of all payments for Medicare Part B covered professional services furnished by the APM Entity group or eligible clinician to all attribution-eligible beneficiaries during the QP Performance Period.

(3) *Claims and adjustments.* In the calculation under paragraph (2), CMS compiles claims and treats claims adjustments, supplemental service payments, and alternative payment methods in the same manner as described in § 414.1450.

(b) *Patient count method.* The threshold score for an APM Entity group or eligible clinician is calculated as a percent under the patient count method by dividing the value described under paragraph (b)(1) of this section by the value described under paragraph (b)(2) of this section.

(1) *Numerator.* The number of attributed beneficiaries to whom the APM Entity group or eligible clinician furnishes Medicare Part B covered professional services during the QP Performance Period.

(2) *Denominator.* The number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B

covered professional services during the QP Performance Period.

(3) *Unique beneficiaries.* For each APM Entity group or eligible clinician, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times.* CMS may count a single Medicare beneficiary in the numerator and/or denominator for multiple different Advanced APM Entities or eligible clinicians.

(c) *Attribution.* (1) Attributed beneficiaries are determined from Advanced APM attribution lists generated by each Advanced APM's specific attribution methodology.

(2) When operationally feasible, this attributed beneficiary list will be the final beneficiary list used for reconciliation purposes in the Advanced APM.

(3) When it is not operationally feasible to use the final attributed beneficiary list, the attributed beneficiary list will be taken from the Advanced APM's most recently available attributed beneficiary list at the end of the QP Performance Period.

(d) *Participation in multiple Advanced APMs.* If the same Advanced APM Entity participates in multiple Advanced APMs and if at least one of those Advanced APMs is an episode payment model, the numerator of the episode payment model Advanced APM Entity will be added to the non-episode payment model Advanced APM Entities' numerator(s), regardless of whether eligible clinicians are identifiable on a Participation List or Affiliated Practitioner List for the Advanced APM Entity. For purposes of this provision, Advanced APM Entities are considered the same if CMS determines that the Participation Lists are substantially similar or if one Advanced APM Entity is a subset of the other.

(e) *Use of methods.* CMS calculates threshold scores for an Advanced APM Entity under both the payment amount and patient count methods for each QP Performance Period. CMS then assigns the higher of the two scores to the Advanced APM Entity.

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

(a) *Payments excluded from calculations.* (1) These calculations include a combination of both Medicare payments for Part B covered professional services and all other payments for all other payers, except payments made by:

(i) The Secretary of Defense for the costs of Department of Defense health care programs.

(ii) The Secretary of Veterans Affairs for the cost of Department of Veterans Affairs health care programs.

(iii) Under Title XIX in a state in which no Medicaid Medical Home Model or APM is available.

(2) Title XIX payments will only be included in the numerator (paragraph (b)(2) of this section) and denominator (paragraph (b)(3) of this section) for an Advanced APM Entity if:

(i) A state has at least one Medicaid Medical Home Model (as defined in § 414.1305) or Medicaid APM (as defined in § 414.1305) in operation that is determined to be an Other Payer Advanced APM; and

(ii) The Advanced APM Entity is eligible to participate in at least one of such Other Payer Advanced APMs during the QP Performance Period, regardless of whether the Advanced APM Entity actually participates in such Other Payer Advanced APMs. This will apply to both the payment amount and patient count methods.

(b) *Payment amount method*—(1) *In general.* The threshold score for an Advanced APM Entity or eligible clinician will be calculated by dividing the value described under the numerator (paragraph (b)(2) of this section) by the value described under the denominator (paragraph (b)(3) of this section).

(2) *Numerator.* The aggregate of all payments from all payers, except those excluded under paragraph (a) of this section, to the Advanced APM Entity group or eligible clinician under the terms of Other Payer Advanced APMs during the QP Performance Period. CMS calculates Medicare Part B covered professional services under the All-Payer Combination Option in the same manner as it is calculated under the Medicare Option.

(3) *Denominator.* The aggregate of all payments from all payers, except those excluded under § 414.1440(a), to the Advanced APM Entity group or eligible clinician during the QP Performance Period. The portion of this amount that relates to Medicare Part B covered professional services is calculated under the All-Payer Combination Option in the same manner as it is calculated under the Medicare Option.

(c) *Patient count method*—(1) *In general.* The Threshold Score for an Advanced APM Entity group or eligible clinician is calculated by dividing the value described under the numerator (paragraph (c)(2) of this section) by the value described under the denominator (paragraph (c)(3) of this section).

(2) *Numerator.* The number of unique patients to whom the Advanced APM Entity group or eligible clinician furnishes services that are included in the measures of aggregate expenditures used under the terms of all of their Other Payer Advanced APMs during the QP Performance Period, plus the patient count numerator under § 414.1435(a)(1).

(3) *Denominator.* The number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services under all non-excluded payers during the QP Performance Period.

(d) *Participation in multiple Other Payer Advanced APMs.* (1) For each APM Entity group or eligible clinician, a unique patient is counted no more than one time for the numerator and no more than one time for the denominator for each payer.

(2) CMS may count a single patient in the numerator and/or denominator for multiple different Advanced APM Entities or eligible clinicians.

(3) If the same Advanced APM Entity participates in two or more Other Payer Advanced APMs and at least one of those Other Payer Advanced APMs is an episode payment model, the numerator of the episode payment model Advanced APM Entity would be added to the non-episode payment model Advanced APM Entities' numerator(s), regardless of whether eligible clinicians are on the Participation List or Affiliated Practitioner List for an Advanced APM Entity.

(4) For purposes of this section, Advanced APM Entities are considered the same entity across Other Payer Advanced APMs if CMS determines that the Participation Lists are substantially similar or if one entity is a subset of the other.

§ 414.1445 Identification of other payer advanced APMs.

(a) *Identification of Medicaid APMs.* For APM Entities and eligible clinicians participating in Medicaid, CMS makes an annual determination prior to the performance period of the existence of Medicaid Medical Home Models and Medicaid APMs, as defined in § 414.1305, in a state based on information obtained from state Medicaid agencies and other relevant sources.

(b) *Obtaining data to calculate the threshold score under the All-Payer Combination Option.* To be assessed under the All-Payer Combination Option, APM Entities or eligible clinicians must submit the following information for each payer in a manner and by a date specified by CMS:

(1) Payment arrangement information necessary to assess the Other Payer APM on all Other Payer Advanced APM criteria under § 414.1420;

(2) For each Other Payer APM, the amount of revenues for services furnished through the arrangement, the total revenues from the payer, the numbers of patients furnished any service through the arrangement, and the total numbers of patients furnished any service through the payer.

(3) An attestation from the payer that the submitted information is accurate.

(c) *Outcome measure.* An Other Payer Advanced APM is required to have payment based on at least one outcome measure.

(1) If an Other Payer Advanced APM has no outcome measure, the Advanced APM Entity must submit an attestation in a manner and by a date determined by CMS that there is no applicable outcome measure on the MIPS list of quality measures.

(2) *Failure to submit adequate information.* (i) CMS makes a QP determination with respect to the individual eligible clinician under the All-Payer Combination Option if:

(A) The eligible clinician's Advanced APM Entity submits the information required under this section for CMS to assess the APM Entity group under the All-Payer Combination Option; and

(B) The eligible clinician submits adequate information under this section.

(ii) If neither the Advanced APM Entity nor the eligible clinician submit the information required under this section, then CMS does not make a QP assessment for such eligible clinician under the All-Payer Combination Option.

§ 414.1450 APM incentive payment.

(a) *In general.* (1) CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section

(2) CMS provides notice of the amount of the APM Incentive Payment to QPs as soon as practicable following the calculation and validation of the APM Incentive Payment amount, but in any event no later than 1 year after the incentive payment base period.

(b) *APM Incentive Payment amount.* (1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act, furnished during the year immediately preceding the payment year.

(2) The estimated aggregate payment amount for covered professional services includes all such payments to any and all of the TIN/NPI combinations associated with the NPI of the QP.

(3) The incentive payment base period, as defined in § 414.1305, is the entire calendar year immediately preceding the payment year.

(4) In calculating the estimated aggregate payment amount for a QP, CMS uses claims submitted with dates of service from January 1 through December 31 of the incentive payment base period, and processing dates of January 1 of the base period through March 31 of the subsequent payment year.

(5) Adjustments, such as use of a completion factor, are not made to the estimated aggregate payment amount.

(6) The payment adjustment amounts, negative or positive, as described in sections 1848(m), (o), (p), and (q) of the Act are not included in calculating the APM Incentive Payment amount.

(7) Incentive payments made to eligible clinicians under sections 1833(m), (x), and (y) of the Act are not included in calculating the APM Incentive Payment amount.

(8) Financial risk payments such as shared savings payments or net reconciliation payments are excluded from the amount of covered professional services in calculating the APM Incentive Payment amount.

(9) Supplemental service payments in the amount of covered professional services are included in calculating the APM Incentive Payment amount according to this paragraph (b). Supplemental service payments are included in the amount of covered professional services when calculating the APM Incentive Payment amount when the supplemental service payment meets the following four criteria:

(i) Is payment for services that constitute physicians services authorized under section 1832(a) and defined under section 1861(s) of the Act.

(ii) Is made for only Part B services under the criterion in paragraph (b)(9)(i) of this section.

(iii) Is directly attributable to services furnished to an individual beneficiary.

(iv) Is directly attributable to an eligible clinician, including an eligible clinician that is a group of individual eligible clinicians.

(v) For payment amounts that are affected by a cash flow mechanism, the payment amounts that would have occurred if the cash flow mechanism were not in place are used in calculating the APM Incentive Payment amount.

(c) *Incentive payment recipient.* (1) CMS pays the entire APM Incentive Payment amount to the TIN associated with the QP's participation in the Advanced APM entity that met the applicable QP threshold during the QP Performance Period.

(2) In the event that an eligible clinician is no longer affiliated with the TIN associated with the QP's participation in the Advanced APM Entity that met the applicable QP threshold during the QP Performance Period, CMS makes the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT Application form.

(3) In the event that an eligible clinician becomes a QP through participation in multiple Advanced APMs, as described in § 414.1425(c)(4)(iii), CMS divides the APM Incentive Payment amount between the TINs associated with the QP's participation in each Advanced APM during the QP Performance Period. Such payments will be divided in proportion to the amount of payments associated with each TIN that the eligible clinician received for covered professional services during the QP Performance Period.

(d) *Timing of the incentive payment.* APM Incentive Payments made under this section are made as soon as practicable following the calculation and validation of the APM Incentive Payment amount, but in any event no later than 1 year after the incentive payment base period.

(e) *Treatment of incentive payment amount in APMs.* (1) APM Incentive Payments made under this section are not included in determining actual expenditures under an APM.

(2) APM Incentive Payments made under this section will not be included in calculations for the purposes of rebasing benchmarks in an APM.

(f) *Treatment of incentive payment amount in other Medicare incentive payments and payment adjustments.* Incentive payments made under this section will not be included in determining the amount of incentive payment made to eligible clinicians under section 1833(m), (x), and (y) of the Act.

§ 414.1455 Limitation on review.

There is no administrative or judicial review under sections 1869, 1878, or otherwise, of the Act of the following:

(a) The determination that an eligible clinician is a QP under § 414.1425 and the determination that an APM Entity is an Advanced APM Entity under § 414.1410.

(b) The determination of the amount of the APM Incentive Payment under § 414.1450, including any estimation as part of such determination.

§ 414.1460 Monitoring and program integrity.

(a) *Vetting eligible clinicians prior to payment of the APM Incentive Payment.* Prior to payment of the APM Incentive Payment, CMS determines if eligible clinicians are in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APMs in which they participate during the QP Performance Period. For QPs not meeting these standards there may be a reduction or denial of the APM Incentive Payment. A determination under this provision is not binding for other purposes.

(b) *Termination by Advanced APMs.* CMS may reduce or deny an APM Incentive Payment to Advanced APM Entities or eligible clinicians who are terminated by APMs for non-compliance with all Medicare conditions of participation or the terms of the relevant Advanced APMS in which they participate during the QP Performance Periods.

(c) *Information submitted for All-Payer Combination Option.* Information submitted by eligible clinicians or Advanced APM Entities to meet the requirements of the All-Payer Combination Option may be subject to audit by CMS. Eligible clinicians and Advanced APM Entities must maintain copies of any supporting documentation related to All-Payer Combination Option for at least 10 years. The APM Incentive Payment will be recouped if an audit reveals a lack of support for attested statements provided by eligible clinicians and Advanced APM Entities.

(d) *Recoupment of APM Incentive Payment.* For any QPs who are terminated from an Advanced APM or found to be in violation of any Federal, state, or tribal laws or regulations during the QP Performance Period or Incentive Payment Base Period or terminated after these periods as a result of a violation occurring during the periods, CMS may rescind such eligible clinicians' QP determinations and, if necessary, recoup part or all of such eligible clinicians' APM Incentive Payments or deduct such amounts from future payments to such individuals. CMS may reopen and recoup any payments that were made in error in accordance with procedures similar to those set forth at 42 CFR 405.980 and 42 CFR 405.370 through 405.379 or established under the relevant APM.

(e) *Maintenance of records.* An Advanced APM Entity or eligible clinician that submits information to CMS under § 414.1445 for assessment under the All-Payer Combination Option must maintain such books contracts, records, documents, and other evidence for a period of 10 years from the final date of the QP Performance Period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Advanced APM Entity of eligible clinician at least 30 days before the formal disposition date; or

(2) There has been a termination, dispute, or allegation of fraud or similar fault against the Advanced APM Entity or eligible clinician, in which case the Advanced APM Entity or eligible clinician must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(f) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the Advanced APM Entity, its eligible clinicians, and other individuals or entities performing functions or services related to its APM activities.

§ 414.1465 Physician-focused payment models.

(a) *Definition.* A physician-focused payment model is an Alternative Payment Model wherein Medicare is a payer, which includes physician group practices or individual physicians as APM Entities and targets the quality and costs of physician services.

(b) *Criteria.* In carrying out its review of physician-focused payment model proposals, the PTAC shall assess whether the physician-focused payment model meets the following criteria for PFPMs sought by the Secretary. The Secretary seeks physician-focused payment models that:

(1) *Incentives: Pay for higher-value care.* (i) Value over volume: Provide incentives to practitioners to deliver high-quality health care.

(ii) Flexibility: Provide the flexibility needed for practitioners to deliver high-quality health care.

(ii) Quality and Cost: Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

(iv) Payment methodology: Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

(v) Scope: Aim to either directly address an issue in payment policy that broadens and expands the APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

(vi) Ability to be evaluated: Have evaluable goals for quality of care, cost, and any other goals of the Physician-focused Payment Model.

(2) *Care delivery improvements: Promote better care coordination, protect patient safety, and encourage patient engagement.* (i) Integration and Care Coordination: Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the Physician-focused Payment Model.

(ii) Patient Choice: Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

(iii) Patient Safety: Aim to maintain or improve standards of patient safety.

(3) *Information Enhancements: Improving the availability of information to guide decision-making.* (i) Health Information Technology: Encourage use of health information technology to inform care.

(ii) [Reserved]

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 4. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 495.4 is amended by revising the definition of "Meaningful EHR user" to read as follows:

§ 495.4 Definitions.

* * * * *

Meaningful EHR user means—

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year, demonstrates in accordance with § 495.40 meaningful use of certified EHR technology by meeting the applicable objectives and associated measures under §§ 495.20, 495.22, and 495.24, supporting information exchange and the prevention of health information blocking and cooperating with the authorized surveillance of health

information technology, and successfully reporting the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable; and

(2)(i) Except as specified in paragraph (2)(ii) of this definition, a Medicaid EP or Medicaid eligible hospital, that meets the requirements of paragraph (1) of this definition and any additional criteria for meaningful use imposed by the State and approved by CMS under §§ 495.316 and 495.332.

(ii) An eligible hospital or CAH is deemed to be a meaningful EHR user for purposes of receiving an incentive payment under subpart D of this part, if the hospital participates in both the Medicare and Medicaid EHR incentive programs, and the hospital meets the requirements of paragraph (1) of this definition.

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or, in the case of a payment adjustment year, during an applicable EHR reporting period for such payment adjustment year) must occur at a practice/location or practices/locations equipped with certified EHR technology.

* * * * *

■ 6. Section 495.40 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Revising paragraphs (a)(2)(i)(E) and (F).

■ c. Adding paragraphs (a)(2)(i)(G), (H) and (I) and (b)(2)(i)(H) and (I).

The revision and additions read as follows:

§ 495.40 Demonstration of meaningful use criteria.

(a) *Demonstration by EPs.* An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.20 or § 495.24, supported information exchange and the prevention of health information blocking, and cooperated with authorized surveillance of health information technology, as follows:

* * * * *

(2) * * *

(i) * * *

(E) For CY 2015 and 2016, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017, the EP may satisfy either the objectives and measures specified in § 495.22(e); or the objectives and measures specified in § 495.24(d).

(G) For CY 2018 and subsequent years, EPs, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

(H) *Cooperation with surveillance of certified EHR technology.* Beginning on April 16, 2016, the EP must attest that he or she cooperated in good faith with the surveillance and ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program, as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the EP in the field.

(I) *Support for health information exchange and the prevention of information blocking.* Beginning on April 16, 2016, the EP must attest that he or she—

(*1*) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(*2*) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times—

(*i*) Connected in accordance with applicable law;

(*ii*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(iii) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*iv*) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.

(*3*) Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(H) *Cooperation with surveillance of certified EHR technology.* Beginning on April 16, 2016, the eligible hospital or CAH must attest that it has cooperated in good faith with the surveillance and ONC direct review of its certified EHR technology certified under the ONC Health IT Certification Program, as authorized by 45 CFR part 170, subpart E, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the eligible hospital or CAH in the field.

(I) *Support for health information exchange and the prevention of information blocking.* Beginning on April 16, 2016, the eligible hospital or CAH must attest that it—

(*1*) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(*2*) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times—

(*i*) Connected in accordance with applicable law;

(*ii*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(*iii*) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*iv*) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.

(*3*) Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

* * * * *

■ 7. Section 495.102 is amended by—

■ a. Revising paragraph (d)(1).

■ b. Revising paragraph (d)(2)(iv).

■ c. Revising paragraph (d)(3).

The revisions read as follows:

§ 495.102 Incentive payments to EPs.

* * * * *

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.* (1) Subject to paragraphs (d)(3) and (4) of this section, for CY 2015 through the end of CY 2018, for covered professional services furnished by an EP who is not hospital-based, and who is not a qualifying EP by virtue of not being a meaningful EHR user (for the EHR reporting period applicable to the payment adjustment year), the payment amount for such services is equal to the product of the applicable percent specified in paragraph (d)(2) of this section and the Medicare physician fee schedule amount for such services.

(2) * * *

(iv) For 2018, 97 percent, except as provided in paragraph (d)(3) of this section.

(3) *Decrease in applicable percent in certain circumstances.* In CY 2018, if the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent must be decreased by 1 percentage point for EPs from the applicable percent in the preceding year.

* * * * *

■ 8. Section 495.316 is amended by revising paragraph (g)(2) and adding paragraph (g)(3) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(g) * * *

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013.

(3) Subject to paragraph (h)(2) of this section, provider-level attestation data for each eligible EP that attests to demonstrating meaningful use for each payment year beginning with 2013 and ending after 2016.

* * * * *

Dated: April 18, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Note: The following Appendix will not appear in the Code of Federal Regulations.

Appendix

TABLE A: Proposed Individual Quality Measures Available for MIPS Reporting in 2017 *(Existing Measures Finalized in CMS-1631-FC).* The 2016 PQRS Measures Specifications Supporting Documents can be found at the following link: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/measurescodes.html.

Note: Existing measures with proposed substantive changes are noted with an asterisk (*), new proposed measures are noted with a plus symbol (+), core measures as agreed upon by Core Measure Collaborative are noted with the symbol (§), high priority measures are noted with an exclamation point (!), and high priority measures that are appropriate use measures are noted with a double exclamation point (!!), in the "MIPS ID Number" column.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
* § !	0059/001	122 v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081/005	135 v4	Effective Clinical Care	Registry, EHR	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
* §	0067/006	N/A	Effective Clinical Care	Registry	Process	**Chronic Stable Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
§	007 0/007	145 v4	Effective Clinical Care	Registry, EHR	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
* §	0083/008	144 v4	Effective Clinical Care	Registry, EHR	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
	0105/ 009	128 v4	Effective Clinical Care	EHR	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
	0086/012	143 v4	Effective Clinical Care	Claims, Registry, EHR	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
	0087/014	N/A	Effective Clinical Care	Claims, Registry	Process	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months.	American Academy of Ophthalmology
	0088/018	167 v4	Effective Clinical Care	EHR	Process	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0089/019	142 v4	Communication and Care Coordination	Claims, Registry, EHR	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!!	0268/021	N/A	Patient Safety	Claims, Registry	Process	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0239/023	N/A	Patient Safety	Claims, Registry	Process	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
							Assurance
!	0045/024	N/A	Communication and Care Coordination	Claims, Registry	Process	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
	0325/032	N/A	Effective Clinical Care	Claims, Registry	Process	**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an antithrombotic at discharge.	American Academy of Neurology
	0046/039	N/A	Effective Clinical Care	Claims, Registry	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
	0134/043	N/A	Effective Clinical Care	Registry	Process	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons
	0236/044	N/A	Effective Clinical Care	Registry	Process	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[1]	Measure Steward
* § !	0097/046	N/A	Communication and Care Coordination	Claims, Web Interface, Registry	Process	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
!	0326/047	N/A	Communication and Care Coordination	Claims, Registry	Process	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
	N/A/048	N/A	Effective Clinical Care	Claims, Registry	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
!	N/A/050	N/A	Person and Caregiver-Centered Experience and Outcomes	Claims, Registry	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
	0091/051	N/A	Effective Clinical Care	Claims, Registry	Process	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented.	American Thoracic Society
	0102/052	N/A	Effective Clinical Care	Claims, Registry	Process	**Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1 less than 60% predicted and have symptoms who were prescribed an inhaled bronchodilator.	American Thoracic Society
!!	0069/065	154 v4	Efficiency and Cost Reduction	Registry, EHR	Process	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
* !!	N/A/066	N/A	Efficiency and Cost Reduction	Registry, EHR	Process	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
	0377/067	N/A	Effective Clinical Care	Registry	Process	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemia: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
	0378/068	N/A	Effective Clinical Care	Registry	Process	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy.	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
	0380/069	N/A	Effective Clinical Care	Registry	Process	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.	American Medical Association-Physician Consortium for Performance Improvement/ American Society of

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
							Hematology
	0379/070	N/A	Effective Clinical Care	Registry	Process	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry:** Percentage of patients aged 18 years and older seen within a 12 month reporting period with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
!	N/A/076	N/A	Patient Safety	Claims, Registry	Process	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
!!	0653/091	N/A	Effective Clinical Care	Claims, Registry	Process	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery
!!	0654/093	N/A	Efficiency and Cost Reduction	Claims, Registry	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	0391/099	N/A	Effective Clinical Care	Claims, Registry	Process	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade.	College of American Pathologists
	0392/100	N/A	Effective Clinical Care	Claims, Registry	Process	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade.	College of American Pathologists

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* § !!	0389/102	129 v5	Efficiency and Cost Reduction	Registry, EHR	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	American Medical Association-Physician Consortium for Performance Improvement
	0390/104	N/A	Effective Clinical Care	Registry	Process	**Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist).	American Medical Association-Physician Consortium for Performance Improvement/ American Urological Association Education and Research
	0104/ 107	161 v4	Effective Clinical Care	EHR	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	American Medical Association-Physician Consortium for Performance Improvement
!	N/A/109	N/A	Person and Caregiver-Centered Experience and Outcomes	Claims, Registry	Process	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
	0041/110	147 v5	Community/Population Health	Claims, Web Interface, Registry, EHR	Process	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-Physician Consortium for Performance Improvement
	0043/111	127 v4	Community/Population Health	Claims, Web Interface, Registry, EHR	Process	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372/112	125 v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Process	**Breast Cancer Screening:** Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance

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§	0034/113	130 v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Process	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ !!	0058/116	N/A	Efficiency and Cost Reduction	Registry	Process	**Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use:** Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance
§	0055/117	131 v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Process	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066/118	N/A	Effective Clinical Care	Registry	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
* §	0062/119	134 v4	Effective Clinical Care	Registry, EHR	Process	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance
!	N/A/122	N/A	Effective Clinical Care	Registry	Intermediate Outcome	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.	Renal Physicians Association
	0417/126	N/A	Effective Clinical Care	Registry	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

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	0416/127	N/A	Effective Clinical Care	Registry	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421/128	69v4	Community/Population Health	Claims, Web Interface, Registry, EHR	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter Normal Parameters: Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
* !	0419/130	68v5	Patient Safety	Claims, Registry, EHR	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
!	0420/131	N/A	Communication and Care Coordination	Claims, Registry	Process	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
*	0418/134	2v5	Community/Population Health	Claims, Web Interface, Registry, EHR	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania

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!	0650/137	N/A	Communication and Care Coordination	Registry	Structure	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/138	N/A	Communication and Care Coordination	Registry	Process	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
	0566/140	N/A	Effective Clinical Care	Claims, Registry	Process	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD.	American Academy of Ophthalmology
!	0563/141	N/A	Communication and Care Coordination	Claims, Registry	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months.	American Academy of Ophthalmology
§ !	0384/143	157 v4	Person and Caregiver-Centered Experience and Outcomes	Registry, EHR	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Medical Association-Physician Consortium for Performance Improvement

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!	0383/144	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
!!	N/A/145	N/A	Patient Safety	Claims, Registry	Process	**Radiology: Exposure Time Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
!	0508/146	N/A	Efficiency and Cost Reduction	Claims, Registry	Process	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign".	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/147	N/A	Communication and Care Coordination	Claims, Registry	Process	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed.	American Medical Association-Physician Consortium for Performance Improvement/ Society of Nuclear Medicine and Molecular Imaging
!	0101/154	N/A	Patient Safety	Claims, Registry	Process	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

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!	0101/155	N/A	Communication and Care Coordination	Claims, Registry	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!!	0382/156	N/A	Patient Safety	Claims, Registry	Process	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	American Society for Radiation Oncology
* §	0405/160	52v4	Effective Clinical Care	EHR	Process	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis.	National Committee for Quality Assurance
* §	0056/163	123v4	Effective Clinical Care	EHR	Process	**Diabetes: Foot Exam:** Percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance
!	0129/164	N/A	Effective Clinical Care	Registry	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
* !	0130/165	N/A	Effective Clinical Care	Registry	Outcome	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons
* !	0131/166	N/A	Effective Clinical Care	Registry	Outcome	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons

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* !	0114/167	N/A	Effective Clinical Care	Registry	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
* !	0115/168	N/A	Effective Clinical Care	Registry	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
*	N/A/176	N/A	Effective Clinical Care	Registry	Process	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
*	N/A/ 177	N/A	Effective Clinical Care	Registry	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.	American College of Rheumatology
	N/A/178	N/A	Effective Clinical Care	Registry	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A/179	N/A	Effective Clinical Care	Registry	Process	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology
*	N/A/180	N/A	Effective Clinical Care	Registry	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease	American College of Rheumatology

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						activity, documentation of glucocorticoid management plan within 12 months.	
!	N/A/181	N/A	Patient Safety	Claims, Registry	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
!	2624/182	N/A	Communication and Care Coordination	Claims, Registry	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
§ !!	0659/185	N/A	Communication and Care Coordination	Claims, Registry	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
*	N/A/187	N/A	Effective Clinical Care	Registry	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well.	American Heart Association/ American Society of Anesthesiologists/ The Joint Commission
!	0565/191	133 v4	Effective Clinical Care	Registry, EHR	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had	American Medical Association-Physician Consortium for

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						best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	Performance Improvement/ National Committee for Quality Assurance
!	0564/192	132 v4	Patient Safety	Registry, EHR	Outcome	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
	0507/195	N/A	Effective Clinical Care	Claims, Registry	Process	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
* §	0068/204	164 v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Process	**Ischemic (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance
§	0409/205	N/A	Effective Clinical Care	Registry	Process	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

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* !	0422/217	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with Knee Impairments:** A self-report measure of change in functional status for patients 18 year+ with knee impairments. The change in functional status assessed using FOTO's (knee) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality.	Focus on Therapeutic Outcomes, Inc.
* !	0423/218	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with Hip Impairments:** A self-report measure of change in functional status for patients 18 years+ with hip impairments. The change in functional status assessed using FOTO's (hip) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality.	Focus on Therapeutic Outcomes, Inc.
* !	0424/219	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with Foot and Ankle Impairments:** A self-report measure of change in functional status for patients 18 years+ with foot and ankle impairments. The change in functional status assessed using FOTO's (foot and ankle) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality.	Focus on Therapeutic Outcomes, Inc.
* !	0425/220	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with Lumbar Impairments:** A self-report outcome measure of functional status for patients 18 years+ with lumbar impairments. The change in functional status assessed using FOTO's (lumbar) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality.	Focus on Therapeutic Outcomes, Inc.
* !	0426/221	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with Shoulder Impairments:** A self-report outcome measure of change in functional status for patients 18 years+ with shoulder impairments. The change in functional status assessed using FOTO's (shoulder) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient	Focus on Therapeutic Outcomes, Inc.

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						level, at the individual clinician, and at the clinic level to assess quality.	
* !	0427/222	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with Elbow, Wrist and Hand Impairments:** A self-report outcome measure of functional status for patients 18 years+ with elbow, wrist and hand impairments. The change in functional status assessed using FOTO's (elbow, wrist and hand) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality.	Focus on Therapeutic Outcomes, Inc.
* !	0428/223	N/A	Communication and Care Coordination	Registry	Outcome	**Functional Status Change for Patients with General Orthopedic Impairments:** A self-report outcome measure of functional status for patients 18 years+ with general orthopedic impairments. The change in functional status assessed using FOTO (general orthopedic) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality.	Focus on Therapeutic Outcomes, Inc.
!!	0562/224	N/A	Efficiency and Cost Reduction	Registry	Process	**Melanoma: Overutilization of Imaging Studies in Melanoma:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
!	0509/225	N/A	Communication and Care Coordination	Claims, Registry	Structure	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
§	0028/226	138 v4	Community/Population Health	Claims, Web Interface, Registry, EHR	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation	American Medical Association-Physician Consortium

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						counseling intervention if identified as a tobacco user.	for Performance Improvement
§ !	0018/236	165 v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
!	0022/238	156 v4	Patient Safety	Registry, EHR	Process	**Use of High-Risk Medications in the Elderly:** Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.	National Committee for Quality Assurance
	0024/239	155 v4	Community/Population Health	EHR	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
	0038/240	117 v4	Community/Population Health	EHR	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
!	0643/243	N/A	Communication and Care Coordination	Registry	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already	American College of Cardiology Foundation/ American Heart Association

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						participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	
	1854/249	N/A	Effective Clinical Care	Claims, Registry	Structure	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	1853/250	N/A	Effective Clinical Care	Claims, Registry	Structure	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	1855/251	N/A	Effective Clinical Care	Claims, Registry	Structure	**Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer.	College of American Pathologists
	0651/254	N/A	Effective Clinical Care	Claims, Registry	Process	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
	N/A/255	N/A	Effective Clinical Care	Claims, Registry	Process	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians
	1519/257	N/A	Effective Clinical Care	Registry	Process	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge.	Society for Vascular Surgeons

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!	N//A/258	N/A	Patient Safety	Registry	Outcome	**Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
!	N/A/259	N/A	Patient Safety	Registry	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
!	N/A/260	N/A	Patient Safety	Registry	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
!	N/A/261	N/A	Communication and Care Coordination	Claims, Registry	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
!	N/A/262	N/A	Patient Safety	Registry	Process	**Image Confirmation of Successful Excision of Image–Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy.	American Society of Breast Surgeons

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	N/A/263	N/A	Effective Clinical Care	Registry	Process	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method.	American Society of Breast Surgeons
	N/A/264	N/A	Effective Clinical Care	Registry	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
!	N/A/265	N/A	Communication and Care Coordination	Registry	Process	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology
*	1814/268	N/A	Effective Clinical Care	Claims, Registry	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.	American Academy of Neurology
§	N/A/271	N/A	Effective Clinical Care	Registry	Process	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year.	American Gastroenterological Association
§	N/A/275	N/A	Effective Clinical Care	Registry	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A/276	N/A	Effective Clinical Care	Registry	Process	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of	American Academy of Sleep Medicine/ American

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						snoring and daytime sleepiness.	Medical Association-Physician Consortium for Performance Improvement
*	N/A/277	N/A	Effective Clinical Care	Registry	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
*	N/A/278	N/A	Effective Clinical Care	Registry	Process	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
*	N/A/279	N/A	Effective Clinical Care	Registry	Process	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
	N/A/281	149 v4	Effective Clinical Care	EHR	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	American Medical Association-Physician Consortium for Performance Improvement
*	N/A/282	N/A	Effective Clinical Care	Registry	Process	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period.	American Academy of Neurology/ American Psychological Association

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*	N/A/283	N/A	Effective Clinical Care	Registry	Process	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period.	American Academy of Neurology/ American Psychological Association
*	N/A/284	N/A	Effective Clinical Care	Registry	Process	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period.	American Academy of Neurology/ American Psychological Association
* !	N/A/286	N/A	Patient Safety	Registry	Process	**Dementia: Counseling Regarding Safety Concerns:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	American Academy of Neurology/ American Psychological Association
* !	N/A/288	N/A	Communication and Care Coordination	Registry	Process	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period.	American Academy of Neurology/ American Psychological Association
*	N/A/290	N/A	Effective Clinical Care	Registry	Process	**Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually.	American Academy of Neurology
*	N/A/291	N/A	Effective Clinical Care	Registry	Process	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually.	American Academy of Neurology
* !	N/A/293	N/A	Communication and Care Coordination	Registry	Process	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually.	American Academy of Neurology

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* !	N/A/294	N/A	Communication and Care Coordination	Registry	Process	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually.	American Academy of Neurology
!	1536/303	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Outcome	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
!	N/A/304	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Outcome	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
	0004/305	137 v4	Effective Clinical Care	EHR	Process	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
* §	0032/309	124 v4	Effective Clinical Care	EHR	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age, who were screened for cervical cancer using either of the following criteria. • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years	National Committee for Quality Assurance
	0033/310	153 v4	Community/Population Health	EHR	Process	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

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§ !!	0052/312	166v5	Efficiency and Cost Reduction	EHR	Process	**Use of Imaging Studies for Low Back Pain:** Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	National Committee for Quality Assurance
!	N/A/316	61v5 & 64v5	Effective Clinical Care	EHR	Intermediate Outcome	**Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL-C) Test Performed AND Risk-Stratified Fasting LDL-C:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed AND percentage of patients aged 20 through 79 years who had a fasting LDL-C test performed and whose risk-stratified fasting LDL-C is at or below the recommended LDL-C goal. *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent OR 10-Year Framingham Risk >20% 2. Moderate Level of Risk: Multiple (2+) Risk Factors OR 10-Year Framingham Risk 10-20% 3. Lowest Level of Risk: 0 or 1 Risk Factor OR 10-Year Framingham Risk <10%.	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
*	N/A/317	22v4	Community/Population Health	Claims, Registry, EHR	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
!	0101/318	139v4	Patient Safety	Web Interface, EHR	Process	**Falls: Screening for Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period.	National Committee for Quality Assurance
§ !!	0658/320	N/A	Communication and Care Coordination	Claims, Registry	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association/ American

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							Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
§ !	0005 & 0006/321	N/A	Person and Caregiver-Centered Experience and Outcomes	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** Summary Survey Measures may include: • Getting Timely Care, Appointments, and Information; • How well Providers Communicate; • Patient's Rating of Provider; • Access to Specialists; • Health Promotion and Education; • Shared Decision-Making; • Health Status and Functional Status; • Courteous and Helpful Office Staff; • Care Coordination; • Between Visit Communication; • Helping You to Take Medication as Directed; and • Stewardship of Patient Resources.	Agency for Healthcare Research & Quality
!!	N/A/322	N/A	Efficiency and Cost Reduction	Registry	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period.	American College of Cardiology
!!	N/A/323	N/A	Efficiency and Cost Reduction	Registry	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
!!	N/A/324	N/A	Efficiency and Cost Reduction	Registry	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR)	American College of Cardiology

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						performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	
!	N/A/325	N/A	Communication and Care Coordination	Registry	Process	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association/American Medical Association-Physician Consortium for Performance Improvement
§	1525/326	N/A	Effective Clinical Care	Claims, Registry	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
* !	N/A/327	N/A	Effective Clinical Care	Registry	Process	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.	Renal Physicians Association
!	1667/328	N/A	Effective Clinical Care	Registry	Intermediate Outcome	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/Dl:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association

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!	N/A/329	N/A	Effective Clinical Care	Registry	Outcome	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated.	Renal Physicians Association
!!	N/A/330	N/A	Patient Safety	Registry	Outcome	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association
!!	N/A/331	N/A	Efficiency and Cost Reduction	Registry	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/332	N/A	Efficiency and Cost Reduction	Registry	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/333	N/A	Efficiency and Cost Reduction	Registry	Efficiency	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/334	N/A	Efficiency and Cost Reduction	Registry	Efficiency	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/335	N/A	Patient Safety	Registry	Outcome	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical	American Medical Association-Physician Consortium for Performance

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						indication.	Improvement
!	N/A/336	N/A	Communication and Care Coordination	Registry	Process	**Maternity Care: Post-Partum Follow-Up and Care Coordination:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning.	American Medical Association-Physician Consortium for Performance Improvement
	N/A/337	N/A	Effective Clinical Care	Registry	Process	**Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
* § !	2082/338	N/A	Effective Clinical Care	Registry	Outcome	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § !	2079/340	N/A	Efficiency and Cost Reduction	Registry	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
!	N/A/342	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Outcome	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
§ !	N/A/343	N/A	Effective Clinical Care	Registry	Outcome	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American College of Gastroenterology/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy

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!	N/A/344	N/A	Effective Clinical Care	Registry	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
!	1543/345	N/A	Effective Clinical Care	Registry	Outcome	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital.	Society for Vascular Surgeons
!	1540/346	N/A	Effective Clinical Care	Registry	Outcome	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA):** Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital.	Society for Vascular Surgeons
!	1534/347	N/A	Patient Safety	Registry	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital:** Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital.	Society for Vascular Surgeons
!	N/A/348	N/A	Patient Safety	Registry	Outcome	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	The Heart Rhythm Society
* !	N/A/350	N/A	Communication and Care Coordination	Registry	Process	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. Nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
* !	N/A/351	N/A	Patient Safety	Registry	Process	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

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* !	N/A/352	N/A	Patient Safety	Registry	Process	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age or gender undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	American Association of Hip and Knee Surgeons
* !	N/A/353	N/A	Patient Safety	Registry	Process	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age or gender undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons
* !	N/A/354	N/A	Patient Safety	Registry	Outcome	**Anastomotic Leak Intervention:** Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
* !	N/A/355	N/A	Patient Safety	Registry	Outcome	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
* !	N/A/356	N/A	Effective Clinical Care	Registry	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
* !	N/A/357	N/A	Effective Clinical Care	Registry	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
!	N/A/358	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

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* !	N/A/359	N/A	Communication and Care Coordination	Registry	Process	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology
* !!	N/A/360	N/A	Patient Safety	Registry	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
* !	N/A/361	N/A	Patient Safety	Registry	Structure	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements.	American College of Radiology
* !	N/A/362	N/A	Communication and Care Coordination	Registry	Structure	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study.	American College of Radiology
* !	N/A/363	N/A	Communication and Care Coordination	Registry	Structure	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or	American College of Radiology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[1]	Measure Steward
						entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.	
* !!	N/A/364	N/A	Communication and Care Coordination	Registry	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.	American College of Radiology
	0108/366	136 v5	Effective Clinical Care	EHR	Process	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
	N/A/367	169 v4	Effective Clinical Care	EHR	Process	**Bipolar Disorder and Major Depression: Appraisal for Alcohol or Chemical Substance Use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health
	N/A/369	158 v4	Effective Clinical Care	EHR	Process	**Pregnant Women that had HBsAg Testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.	OptumInsight
* § !	0710/370	159 v4	Effective Clinical Care	Web Interface, Registry, EHR	Outcome	**Depression Remission at Twelve Months:** Patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire (PHQ-9) score greater than nine who demonstrate remission at twelve months (+/- 30 days) after an index visit) defined as a PHQ-9 score less than five. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a	Minnesota Community Measurement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[1]	Measure Steward
						need for treatment.	
	0712/371	160v4	Effective Clinical Care	EHR	Process	**Depression Utilization of the PHQ-9 Tool:** Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit.	Minnesota Community Measurement
	N/A/372	82v3	Community/Population Health	EHR	Process	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.	National Committee for Quality Assurance
!	N/A/373	65v5	Effective Clinical Care	EHR	Intermediate Outcome	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
!	N/A/374	50v4	Communication and Care Coordination	EHR	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services/ Mathematica
* !	N/A/375	66v4	Person and Caregiver-Centered Experience and Outcomes	EHR	Process	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients aged 18 years of age and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
* !	N/A/376	56v4	Person and Caregiver-Centered Experience and Outcomes	EHR	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments.	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
* !	N/A/377	90v4	Person and Caregiver-Centered Experience and Outcomes	EHR	Process	**Functional Status Assessment for Patients with Congestive Heart Failure:** Percentage of patients aged 65 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services/ Mathematica

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
!	N/A/378	75v4	Community/Population Health	EHR	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services/ Mathematica
	N/A/379	74v5	Effective Clinical Care	EHR	Process	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
!	1365/382	177v4	Patient Safety	EHR	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	American Medical Association-Physician Consortium for Performance Improvement
!	1879/383	N/A	Patient Safety	Registry	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group/ Centers for Medicare & Medicaid Services
!	N/A/384	N/A	Effective Clinical Care	Registry	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
!	N/A/385	N/A	Effective Clinical Care	Registry	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology/ The Australian Council on Healthcare Standards
!	N/A/386	N/A	Person and Caregiver-Centered Experienc	Registry	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive	American Academy of Neurology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
			e and Outcomes			ventilation, hospice) at least once annually.	
	N/A/387	N/A	Effective Clinical Care	Registry	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period.	American Medical Association-Physician Consortium for Performance Improvement
!	N/A/388	N/A	Patient Safety	Registry	Outcome	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy:** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology/American College of Healthcare Sciences
!	N/A/389	N/A	Effective Clinical Care	Registry	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology/American College of Healthcare Sciences
!	N/A/390	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Process	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
!	0576/391	N/A	Communication and Care Coordination	Registry	Process	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported: - The percentage of discharges for which the patient received follow-up within 30 days of	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
						discharge - The percentage of discharges for which the patient received follow-up within 7 days of discharge.	
!	2474/392	N/A	Patient Safety	Registry	Outcome	**HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation This measure is reported as four rates stratified by age and gender: • Reporting Age Criteria 1: Females less than 65 years of age • Reporting Age Criteria 2: Males less than 65 years of age • Reporting Age Criteria 3: Females 65 years of age and older • Reporting Age Criteria 4: Males 65 years of age and older	The Heart Rhythm Society
!	N/A/393	N/A	Patient Safety	Registry	Outcome	**HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	The Heart Rhythm Society
	1407/394	N/A	Community/Population Health	Registry	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
!	N/A/395	N/A	Communication and Care Coordination	Claims, Registry	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report.	College of American Pathologists
!	N/A/396	N/A	Communication and Care Coordination	Claims, Registry	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type.	College of American Pathologists
!	N/A/397	N/A	Communication and Care Coordination	Claims, Registry	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.	College of American Pathologists

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
!	N/A/398	N/A	Effective Clinical Care	Registry	Outcome	**Optimal Asthma Control:** Patients ages 5-50 (pediatrics ages 5-17) whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	Minnesota Community Measurement
§	N/A/400	N/A	Effective Clinical Care	Registry	Process	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection.	American Medical Association-Physician Consortium for Performance Improvement
§	N/A/401	N/A	Effective Clinical Care	Registry	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
	N/A/402	N/A	Community/Population Health	Registry	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance/National Collaborative for Innovation in Quality Measurement
!	N/A/403‡	N/A	Person and Caregiver-Centered Experience and Outcomes	Registry	Process	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association/American Medical Association-Physician Consortium for Performance Improvement
!	N/A/404‡	N/A	Effective Clinical Care	Registry	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
	N/A/405‡	N/A	Effective Clinical Care	Claims, Registry	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: •Liver lesion ≤ 0.5 cm •Cystic kidney lesion < 1.0 cm •Adrenal lesion ≤ 1.0 cm	American College of Radiology
!!	N/A/406 ‡	N/A	Effective Clinical Care	Claims, Registry	Process	**Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT) or magnetic resonance imaging (MRI) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
!!	N/A/407‡	N/A	Effective Clinical Care	Claims, Registry	Process	**Appropriate Treatment of MSSA Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.	Infectious Disease Society of America
	N/A/408‡	N/A	Effective Clinical Care	Registry	Process	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
!	N/A/409‡	N/A	Effective Clinical Care	Registry	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
!	N/A/410‡	N/A	Person and Caregiver-Centered Experience and Outcomes	Claims, Registry	Outcome	**Psoriasis: Clinical Response to Oral Systemic or Biologic Medications:** Percentage of psoriasis patients receiving oral systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology

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!	0711/411 ‡	N/A	Communication and Care Coordination	Registry	Outcome	**Depression Remission at Six Months:** Adult patients age 18 years and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at six months defined as a PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.	Minnesota Community Measurement
	N/A/412‡	N/A	Effective Clinical Care	Registry	Process	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
!	N/A/413‡	N/A	Effective Clinical Care	Registry	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
	N/A/414‡	N/A	Effective Clinical Care	Registry	Process	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
!	N/A/415‡	N/A	Efficiency and Cost Reduction	Claims, Registry	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
!!	N/A/416‡	N/A	Efficiency and Cost Reduction	Claims, Registry	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network prediction rules for traumatic brain injury.	American College of Emergency Physicians

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
!	1523/417 ‡	N/A	Patient Safety	Registry	Outcome	**Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
	0053/418 ‡	N/A	Effective Clinical Care	Claims, Registry	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!!	N/A/419‡	N/A	Efficiency and Cost Reduction	Claims, Registry	Efficiency	**Overuse Of Neuroimaging For Patients With Primary Headache And A Normal Neurological Examination:** Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered.	American Academy of Neurology
*	N/A/420‡	N/A	Effective Clinical Care	Registry	Outcome	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
*	N/A/421‡	N/A	Effective Clinical Care	Registry	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
!	2063/422 ‡	N/A	Patient Safety	Claims, Registry	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
	0465/423 ‡	N/A	Effective Clinical Care	Claims, Registry	Process	**Perioperative Anti-platelet Therapy for Patients undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent (aspirin or clopidogrel or equivalent such as aggrenox/tiglacor, etc.) within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery.	Society for Vascular Surgeons
!	2671/424 ‡	N/A	Patient Safety	Registry	Process	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
!	N/A/426‡	N/A	Communication and Care Coordination	Registry	Process	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists
!	N/A/427‡	N/A	Communication and Care Coordination	Registry	Process	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists
	N/A/428‡	N/A	Effective Clinical Care	Registry	Process	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation for the indication of stress urinary incontinence per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
!	N/A/429‡	N/A	Patient Safety	Claims, Registry	Process	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to surgery for pelvic organ prolapse.	American Urogynecologic Society

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!	N/A/430‡	N/A	Patient Safety	Registry	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	American Society of Anesthesiologists
	2152/431‡	N/A	Community/Population Health	Registry	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user.	American Medical Association-Physician Consortium for Performance Improvement
!	N/A/432‡	N/A	Patient Safety	Registry	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery.	American Urogynecologic Society
!	N/A/433‡	N/A	Patient Safety	Registry	Outcome	**Proportion of Patients Sustaining a Major Viscus Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by perforation of a major viscus at the time of index surgery that is recognized intraoperative or within 1 month after surgery.	American Urogynecologic Society
!	N/A/434‡	N/A	Patient Safety	Registry	Outcome	**Proportion of Patients Sustaining A Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing a pelvic organ prolapse repair who sustain an injury to the ureter recognized either during or within 1 month after surgery.	American Urogynecologic Society
!	N/A/435‡	N/A	Effective Clinical Care	Claims, Registry	Outcome	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved.	American Academy of Neurology

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	N/A/436‡	N/A	Effective Clinical Care	Claims, Registry	Process	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Use of iterative reconstruction technique	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	N/A/437‡	N/A	Patient Safety	Claims, Registry	Outcome	**Rate of Surgical Conversion from Lower Extremity Endovascular Revasculatization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	Society of Interventional Radiology
	N/A/438‡	N/A	Effective Clinical Care	Web Interface, Registry	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
§ !!	N/A/439‡	N/A	Efficiency and Cost Reduction	Registry	Efficiency	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
+ !	N/A/New		Communication and Care Coordination	Claims, Registry	Process	**Non-melanoma Skin Cancer (NMSC): Biopsy Reporting Time – Pathologist:** Length of time taken from when the pathologist completes the final biopsy report to when s/he sends the final report to the biopsying physician. This measure evaluates the reporting time between pathologist and biopsying clinician.	American Academy of Dermatology
+ !	N/A/New		Effective Clinical Care	Registry	Intermediate Outcome	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: Most recent blood pressure measurement is less than 140/90 mm Hg -- And Most recent tobacco status is Tobacco Free -- And Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And Statin Use.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
+ §	0071/New		Effective Clinical Care	Registry	Process	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged alive from 6 months prior to the beginning of the measurement year through the 6 months after the beginning of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance
+ § !!	N/A/New		Patient Safety	Registry	Process	**Non-recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age unnecessarily screened for cervical cancer.	National Committee for Quality Assurance
+ § !	1799/New		Efficiency and Cost Reduction	Registry	Process	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period. Two rates are reported. 1. The percentage of patients who remained on an asthma controller medication for at least 50% of their treatment period. 2. The percentage of patients who remained on an asthma controller medication for at least 75% of their treatment period.	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
+ § !	0119/New		Effective Clinical Care	Registry	Outcome	**Risk-Adjusted Operative Mortality for CABG:** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	The Society of Thoracic Surgeons
+ § !	0733/New		Patient Safety	Registry	Outcome	**Operative Mortality Stratified by the Five STS-EACTS Mortality Categories:** Percent of patients undergoing index pediatric and/or congenital heart surgery who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days (including patients transferred to other acute care facilities), and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, stratified by the five STAT Mortality Levels, a multi-institutional validated complexity stratification tool.	The Society of Thoracic Surgeons
+ §	1395/New		Community/Population Health	Registry	Process	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 18 years of age who had a chlamydia screening test with proper follow-up.	National Committee for Quality Assurance
+ § !	0567/New		Patient Safety	Registry	Process	**Appropriate Work Up Prior to Endometrial Ablation Procedure:** To ensure that all women have endometrial sampling performed before undergoing an endometrial ablation	Health Benchmarks – IMS Health
+ § !!	1857/New		Efficiency and Cost Reduction	Registry	Process	**Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab:** Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu negative who are not administered trastuzumab.	American Society of Clinical Oncology
+ § !!	1858/New		Efficiency and Cost Reduction	Registry	Process	**Trastuzumab administered to patients with AJCC stage I (T1c) – III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy:** Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu negative who are not administered trastuzumab.	American Society of Clinical Oncology
+ §	1859/New		Effective Clinical Care	Registry	Process	**American Society of Clinical Oncology:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed.	American Society of Clinical Oncology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data submission Method	Measure Type	Measure Title and Description¥	Measure Steward
+ § !!	1860/New		Patient Safety	Registry	Process	**Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
+ § !!	0210/New		Effective Clinical Care	Registry	Process	**Proportion receiving chemotherapy in the last 14 days of life:** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
+ § !!	0211/New		Effective Clinical Care	Registry	Outcome	**Proportion with more than one emergency room visit in the last 30 days of life:** Percentage of patients who died from cancer with more than one emergency room visit in the last days of life.	American Society of Clinical Oncology
+ § !!	0213/New		Effective Clinical Care	Registry	Outcome	**Proportion admitted to the ICU in the last 30 days of life:** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
+ § !!	0215/New		Effective Clinical Care	Registry	Process	**Proportion not admitted to hospice:** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology
+ § !!	0216/New		Effective Clinical Care	Registry	Outcome	**Proportion admitted to hospice for less than 3 days:** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology

‡ This measure was new to the Physician Quality Reporting System and was adopted for reporting beginning in CY 2016.

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

TABLE B: Proposed Existing Quality Measures That Are Calculated for 2017 MIPS Performance That Do Not Require Data Submission

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Type	Measure Title and Description[¥]	Measure Steward
	N/A	N/A	Communication and Care Coordination	Outcome	**Acute Conditions Composite:** • Bacterial Pneumonia (PQI 11) (NQF 0279) • Urinary Tract Infection (PQI 12) (NQF 0281) • Dehydration (PQI 10) (NQF 0280)	Agency for Healthcare Research & Quality
	N/A	N/A	Communication and Care Coordination	Outcome	**Chronic Conditions Composite:** • Diabetes (composite of 4 indicators) (PQI 03, 01, 14, 16) (NQF 0274, 0272,0285, 0638) • Chronic Obstructive Pulmonary Disease or Asthma (PQI 5) (NQF 0275) • Heart Failure (PQI 8) (NQF 0277)	Agency for Healthcare Research & Quality
	1789/N/A	N/A	Communication and Care Coordination	Outcome	**All-cause Hospital Readmission Measure:** The 30-day All-Cause Hospital Readmission measure is a risk-standardized readmission rate for beneficiaries age 65 or older who were hospitalized at a short-stay acute care hospital and experienced an unplanned readmission for any cause to an acute care hospital within 30 days of discharge. The measure applies to solo practitioners and groups of practitioners, as identified by their Taxpayer Identification Number (TIN).	Yale University

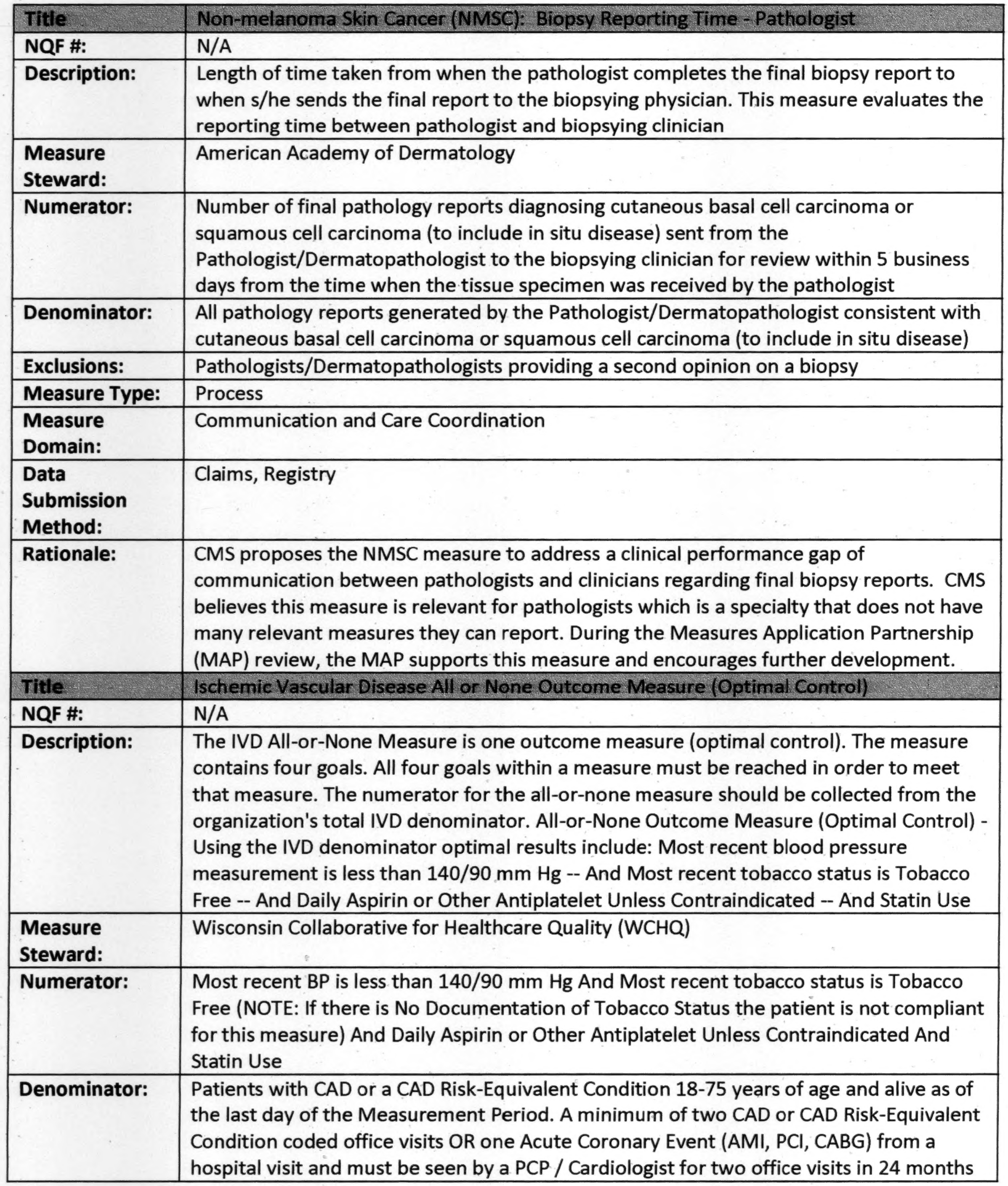
TABLE C: Proposed Individual Quality Cross-Cutting Measures for the MIPS to Be Available to Meet the Reporting Criteria Via Claims, Registry, and EHR Beginning in 2017

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data Submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
!	0326 /047	N/A	Communication and Care Coordination	Claims, Registry	Process	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data Submission Method	Measure Type	Measure Title and Description[¥]	Measure Steward
* !	0419 /130	68v5	Patient Safety	Claims, Registry, EHR	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
§	0028 /226	138v4	Community/ Population Health	Claims, Web Interface, Registry, EHR	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	American Medical Association-Physician Consortium for Performance Improvement
§ !	0018 /236	165v4	Effective Clinical Care	Claims, Web Interface, Registry, EHR	Intermediate Outcome	**Controlling: High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
*	N/A/ 317	22v4	Community/ Population Health	Claims, Registry, EHR	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
!	N/A/ 374	50v4	Communication and Care Coordination	EHR	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services/ Mathematica
	N/A/ 402	N/A	Community/ Population Health	Registry	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance/ National Collaborative for Innovation in Quality Measurement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Data Submission Method	Measure Type	Measure Title and Description¥	Measure Steward
	2152 /431	N/A	Community/ Population Health	Registry	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user	American Medical Association-Physician Consortium for Performance Improvement
* §	0421 /128	69v4	Community/Population Health	Claims, Web Interface, Registry, EHR	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
§ !	0005 & 0006 /321	N/A	Person and Caregiver-Centered Experience and Outcomes	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPS Clinician/Group Survey:** Summary Survey Measures may include: • Getting Timely Care, Appointments, and Information; • How well Providers Communicate; • Patient's Rating of Provider; • Access to Specialists; • Health Promotion and Education; • Shared Decision-Making; • Health Status and Functional Status; • Courteous and Helpful Office Staff; • Care Coordination; • Between Visit Communication; • Helping You to Take Medication as Directed; and • Stewardship of Patient Resources.	Agency for Healthcare Research & Quality

TABLE D: Proposed New Measures for MIPS Reporting in 2017



Title	Non-melanoma Skin Cancer (NMSC): Biopsy Reporting Time - Pathologist
NQF #:	N/A
Description:	Length of time taken from when the pathologist completes the final biopsy report to when s/he sends the final report to the biopsying physician. This measure evaluates the reporting time between pathologist and biopsying clinician
Measure Steward:	American Academy of Dermatology
Numerator:	Number of final pathology reports diagnosing cutaneous basal cell carcinoma or squamous cell carcinoma (to include in situ disease) sent from the Pathologist/Dermatopathologist to the biopsying clinician for review within 5 business days from the time when the tissue specimen was received by the pathologist
Denominator:	All pathology reports generated by the Pathologist/Dermatopathologist consistent with cutaneous basal cell carcinoma or squamous cell carcinoma (to include in situ disease)
Exclusions:	Pathologists/Dermatopathologists providing a second opinion on a biopsy
Measure Type:	Process
Measure Domain:	Communication and Care Coordination
Data Submission Method:	Claims, Registry
Rationale:	CMS proposes the NMSC measure to address a clinical performance gap of communication between pathologists and clinicians regarding final biopsy reports. CMS believes this measure is relevant for pathologists which is a specialty that does not have many relevant measures they can report. During the Measures Application Partnership (MAP) review, the MAP supports this measure and encourages further development.
Title	Ischemic Vascular Disease All or None Outcome Measure (Optimal Control)
NQF #:	N/A
Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: Most recent blood pressure measurement is less than 140/90 mm Hg -- And Most recent tobacco status is Tobacco Free -- And Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And Statin Use
Measure Steward:	Wisconsin Collaborative for Healthcare Quality (WCHQ)
Numerator:	Most recent BP is less than 140/90 mm Hg And Most recent tobacco status is Tobacco Free (NOTE: If there is No Documentation of Tobacco Status the patient is not compliant for this measure) And Daily Aspirin or Other Antiplatelet Unless Contraindicated And Statin Use
Denominator:	Patients with CAD or a CAD Risk-Equivalent Condition 18-75 years of age and alive as of the last day of the Measurement Period. A minimum of two CAD or CAD Risk-Equivalent Condition coded office visits OR one Acute Coronary Event (AMI, PCI, CABG) from a hospital visit and must be seen by a PCP / Cardiologist for two office visits in 24 months

	and one office visit in 12 months
Exclusions:	History of Gastrointestinal Bleed or Intra-cranial Bleed or documentation of active anticoagulant use during the MP for the Aspirin/Other Anticoagulant component (numerator) of the measure. Inpatient Stays, Emergency Room Visits, Urgent Care Visits, and Patient Self-Reported BP's (Home and Health Fair BP results) for the Blood Pressure Control component (numerator) of the composite measure
Measure Type:	Intermediate Outcome
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS proposes the All or None (Composite) measure because it provides benefits to both the patient and the practitioner. CMS believes this measure closely reflects the interests and likely desires of the patient which is a high priority of CMS. Secondly, this measure is an outcome measure that represents a systems perspective emphasizing the importance of optimal care through a patient's entire healthcare experience. During the Measures Application Partnership (MAP) review, the MAP conditionally supports this measure for implementation in 2017. However, the MAP would like to see a future measure that includes patient compliance as part of the composite.
Title	**Persistent Beta Blocker Treatment After a Heart Attack**
NQF #:	0071
Description:	The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged alive from 6 months prior to the beginning of the measurement year through the 6 months after the beginning of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received persistent beta-blocker treatment for six months after discharge
Measure Steward:	National Committee for Quality Assurance
Numerator:	Patients who had a 180-day course of treatment with beta-blockers post discharge
Denominator:	Patients 18 years of age and older by the end of the measurement year who were discharged alive from an acute inpatient setting with an AMI from 6 months prior to the beginning of the measurement year through the 6 months after the beginning of the measurement year
Exclusions:	Exclude patients who are identified as having an intolerance or allergy to beta-blocker therapy. Look as far back as possible in the patient's history for evidence of a contraindication to beta-blocker therapy Exclude from the denominator hospitalizations in which the patient was transferred directly to a non-acute care facility for any diagnosis
Measure Type:	Process
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of

	condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address cardiovascular care. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Non-recommended Cervical Cancer Screening in Adolescent Females
NQF #:	N/A
Description:	The percentage of adolescent females 16–20 years of age unnecessarily screened for cervical cancer
Measure Steward:	National Committee for Quality Assurance
Numerator:	Cervical cytology (Cervical Cytology Value Set) or an HPV test (HPV Tests Value Set) performed during the measurement year
Denominator:	Adolescent females 16-20 years as of December 31 of the measurement year
Exclusions:	A history of cervical cancer (Cervical Cancer Value Set), HIV (HIV Value Set) or immunodeficiency (Disorders of the Immune System Value Set) any time during the member's history through December 31 of the measurement year
Measure Type:	Process
Measure Domain:	Patient Safety
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address care coordination and patient safety within primary care. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Medication Management for People with Asthma (MMA)
NQF #:	1799
Description:	The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period. Two rates are reported 1. The percentage of patients who remained on an asthma controller medication for at least 50% of their treatment period 2. The percentage of patients who remained on an asthma controller medication for at least 75% of their treatment period
Measure Steward:	National Committee for Quality Assurance
Numerator:	Medication Compliance 50%: The number of patients who achieved a PDC* of at least 50% for their asthma controller medications during the measurement year Medication Compliance 75%: The number of patients who achieved a PDC* of at least 75% for their asthma controller medications during the measurement year

	*PDC is the proportion of days covered by at least one asthma controller medication prescription, divided by the number of days in the treatment period
Denominator:	Patients 5–64 years of age during the measurement year who were identified as having persistent asthma
Exclusions:	1) Exclude patients who had any diagnosis of Emphysema (Emphysema Value Set, Other Emphysema Value Set), COPD (COPD Value Set), Chronic Bronchitis (Obstructive Chronic Bronchitis Value Set, Chronic Respiratory Conditions Due To Fumes/Vapors Value Set), Cystic Fibrosis (Cystic Fibrosis Value Set) or Acute Respiratory Failure (Acute Respiratory Failure Value Set) any time during the patient's history through the end of the measurement year (e.g., December 31) 2) Exclude any patients who have no asthma controller medications (Table ASM-D) dispensed during the measurement year
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
Data Submission Method	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address pulmonary care within primary care. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Risk-Adjusted Operative Mortality for CABG
NQF #:	0119
Description:	Percent of patients aged 18 years and older undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure
Measure Steward:	The Society of Thoracic Surgeons
Numerator:	Number of patients undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure
Denominator:	All patients undergoing isolated CABG
Exclusions:	N/A
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry

Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address chronic cardiovascular condition. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Operative Mortality Stratified by the Five STS-EACTS Mortality Categories
NQF #:	0733
Description:	Percent of patients undergoing index pediatric and/or congenital heart surgery who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days (including patients transferred to other acute care facilities), and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, stratified by the five STAT Mortality Levels, a multi-institutional validated complexity stratification tool
Measure Steward:	The Society of Thoracic Surgeons
Numerator:	Number of patients undergoing index pediatric and/or congenital heart surgery who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days (including patients transferred to other acute care facilities), and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, stratified by the five STAT Mortality Levels, a multi-institutional validated complexity stratification tool
Denominator:	All patients undergoing index pediatric and/or congenital heart surgery
Exclusions:	N/A
Measure Type:	Outcome
Measure Domain:	Patient Safety
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address pediatric heart surgery. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Chlamydia Screening and Follow-up
NQF #:	1395
Description:	The percentage of female adolescents 18 years of age who had a chlamydia screening test with proper follow-up
Measure Steward:	National Committee for Quality Assurance
Numerator:	Adolescents who had documentation of a chlamydia screening test with proper follow-up by the time they turn 18 years of age
Denominator:	Sexually active female adolescents with a visit who turned 18 years of age during the

	measurement year
Exclusions:	N/A
Measure Type:	Process
Measure Domain:	Community/Population Health
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address obstetrics and gynecology conditions. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Appropriate Work Up Prior to Endometrial Ablation Procedure
NQF #:	0567
Description:	To ensure that all women have endometrial sampling performed before undergoing an endometrial ablation
Measure Steward:	Health Benchmarks – IMS Health
Numerator:	Women who received endometrial sampling or hysteroscopy with biopsy during the year prior to the index date (inclusive of the index date)
Denominator:	Continuously enrolled women who had an endometrial ablation procedure during the measurement year
Exclusions:	Women who had an endometrial ablation procedure during the year prior to the index date (exclusive of the index date)
Measure Type:	Process
Measure Domain:	Patient Safety
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address obstetrics and gynecology conditions. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	1857 - Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab
NQF #:	1857
Description:	Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu negative who are not administered trastuzumab
Measure Steward:	American Society of Clinical Oncology

Numerator:	Trastuzumab not administered during the initial course of treatment
Denominator:	Adult women with AJCC stage I (T1c) – III breast cancer that is HER-2 negative or HER-2 undocumented/unknown
Exclusions:	Patient transfer to practice after initiation of chemotherapy
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address medical oncology and breast cancer. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Trastuzumab administered to patients with AJCC stage I (T1c) – III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy
NQF #:	1858
Description:	Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu negative who are not administered trastuzumab
Measure Steward:	American Society of Clinical Oncology
Numerator:	Trastuzumab not administered during the initial course of treatment
Denominator:	Adult women with AJCC stage I (T1c) – III breast cancer that is HER-2 negative or HER-2 undocumented/unknown
Exclusions:	Patient transfer to practice after initiation of chemotherapy
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address medical oncology and breast cancer. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
NQF #:	1859
Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom

	KRAS gene mutation testing was performed
Measure Steward:	American Society of Clinical Oncology
Numerator:	KRAS gene mutation testing performed before initiation of anti-EGFR MoAb
Denominator:	Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy
Exclusions:	Patient transfer to practice after initiation of chemotherapy
Measure Type:	Process
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address medical oncology and breast cancer. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
NQF #:	1860
Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies
Measure Steward:	American Society of Clinical Oncology
Numerator:	Anti-EGFR monoclonal antibody therapy not received
Denominator:	Adult patients with metastatic colorectal cancer who have a KRAS gene mutation
Exclusions:	Patient transfer to practice after initiation of chemotherapy Receipt of anti-EGFR monoclonal antibody therapy as part of a clinical trial protocol
Measure Type:	Process
Measure Domain:	Patient Safety
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address medical oncology and breast cancer. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Proportion receiving chemotherapy in the last 14 days of life
NQF #:	0210

Description:	Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life
Measure Steward:	**American Society of Clinical Oncology**
Numerator:	Patients who died from cancer and received chemotherapy in the last 14 days of life
Denominator:	Patients who died from cancer
Exclusions:	N/A
Measure Type:	Process
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address hospice and end of life metrics for medical oncology. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Proportion with more than one emergency room visit in the last 30 days of life
NQF #:	0211
Description:	Percentage of patients who died from cancer with more than one emergency room visit in the last days of life
Measure Steward:	**American Society of Clinical Oncology**
Numerator:	Patients who died from cancer and had >1 ER visit in the last 30 days of life
Denominator:	Patients who died from cancer
Exclusions:	N/A
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address hospice and end of life metrics for medical oncology. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Proportion admitted to the ICU in the last 30 days of life
NQF #:	0213
Description:	Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life
Measure	**American Society of Clinical Oncology**

Steward:	
Numerator:	Patients who died from cancer and were admitted to the ICU in the last 30 days of life
Denominator:	Patients who died from cancer
Exclusions:	N/A
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address hospice and end of life metrics for medical oncology. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Proportion not admitted to hospice
NQF #:	0215
Description:	Percentage of patients who died from cancer not admitted to hospice
Measure Steward:	**American Society of Clinical Oncology**
Numerator:	Patients who died from cancer without being admitted to hospice
Denominator:	Patients who died from cancer
Exclusions:	N/A
Process Type:	Process
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address hospice and end of life metrics for medical oncology. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).
Title	Proportion admitted to hospice for less than 3 days
NQF #:	0216
Description:	Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there
Measure Steward:	**American Society of Clinical Oncology**
Numerator:	Patients who died from cancer and spent fewer than three days in hospice
Denominator:	Patients who died from cancer who were admitted to hospice
Exclusions:	N/A

Measure Type:	Outcome
Measure Domain:	Effective Clinical Care
Data Submission Method:	Registry
Rationale:	CMS, as part of the core measure collaborative, proposes this measure to fulfill a set of condition-specific core measures. CMS believes the core measure collaborative fills measure gaps, condition-specific performance gaps and ensures the collaborative agreement between CMS and private health insurers. This measure is proposed as a core measure to specifically address hospice and end of life metrics for medical oncology. Furthermore, CMS is utilizing its authority to propose measures that were not reviewed by the Measures Application Partnership (MAP).

TABLE E: 2017 Proposed MIPS Specialty Measure Sets

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						1. Allergy/Immunology/Rheumatology	
	0041/ 110	147v5	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	Preventive Care and Screening: Influenza Immunization Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	American Medical Association-Physician Consortium for Performance Improvement
	0043/ 111	127v4	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	Pneumonia Vaccination Status for Older Adults Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
* §	0405/ 160	52v4	EHR	Process	Effective Clinical Care	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis	National Committee for Quality Assurance
*	N/A/ 176	N/A	Registry	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Tuberculosis Screening Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)	American College of Rheumatology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
1. Allergy/Immunology/Rheumatology							
*	N/A/ 177	N/A	Registry	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months	American College of Rheumatology
	N/A/ 178	N/A	Registry, Measures Group	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Functional Status Assessment Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months	American College of Rheumatology
*	N/A/ 179	N/A	Registry	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months	American College of Rheumatology
*	N/A/ 180	N/A	Registry	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Glucocorticoid Management Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	American College of Rheumatology
!!	N/A/331	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse) Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 332	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
1. Allergy/Immunology/Rheumatology							
!!	N/A/ 334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
	N/A/ 337	N/A	Registry	Process	Effective Clinical Care	Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
!	N/A/ 398	N/A	Registry	Process	Efficiency and Cost Reduction	Optimal Asthma Control Patients ages 5-50 (pediatrics ages 5-17) whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools	Minnesota Community Measurement
+ § !	1799/ NA	NA	Registry	Process	Efficiency and Cost Reduction	Medication Management for People with Asthma (MMA): The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period. Two rates are reported. 1. The percentage of patients who remained on an asthma controller medication for at least 50% of their treatment period. 2. The percentage of patients who remained on an asthma controller medication for at least 75% of their treatment period.	National Committee for Quality Assurance

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered a patient-facing provider, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
2. Anesthesiology							
!	N/A/ 076	N/A	Claims, Registry	Process	Patient Safety	Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed	American Society of Anesthesiologists
!	N/A/ 404	N/A	Registry	Intermediate Outcome	Effective Clinical Care	Anesthesiology Smoking Abstinence The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
!	2681 /424	N/A	Registry	Process	Patient Safety	Perioperative Temperature Management Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time	American Society of Anesthesiologists
!	N/A/ 426	N/A	Registry	Process	Communication and Care Coordination	Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized	American Society of Anesthesiologists
!	N/A/ 427	N/A	Registry	Process	Communication and Care Coordination	Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU) Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member	American Society of Anesthesiologists

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			2. Anesthesiology				
!	N/A/ 430	N/A	Registry	Process	Patient Safety	Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively	American Society of Anesthesiologists
	0236 /044	N/A	Registry	Process	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			3. Cardiology				
§	0081 /005	135v4	Registry, EHR	Process	Effective Clinical Care	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD) Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
* §	0083 /008	144v4	Registry, EHR	Process	Effective Clinical Care	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Medical Association-

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
3. Cardiology							
						Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
* §	0066 /118	N/A	Registry	Process	Effective Clinical Care	Chronic Stable Coronary Artery Disease: ACE Inhibitor or ARB Therapy--Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%) Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
* §	0067 /006	N/A	Registry	Process	Effective Clinical Care	Chronic Stable Coronary Artery Disease: Antiplatelet Therapy Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
§	0070 /007	145v4	Registry, EHR	Process	Effective Clinical Care	Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%) Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
3. Cardiology							
§	1525 /326	N/A	Claims, Registry	Process	Effective Clinical Care	Chronic Anticoagulation Therapy Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance
	N/A/ 438	N/A	Web Interface, Registry	Process	Effective Clinical Care	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
§	0070 /007	145v4	Registry, EHR	Process	Effective Clinical Care	Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%) Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						3. Cardiology	
* §	0068 /204	164v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance
!!	N/A/ 322	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period	American College of Cardiology
!!	N/A/ 323	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI) Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status	American College of Cardiology
!!	N/A/ 324	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment	American College of Cardiology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
3. Cardiology							
3a. Electrophysiology Cardiac Specialist							
!	N/A/ 348	N/A	Registry	Outcome	Patient Safety	HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD	The Heart Rhythm Society
!	2474 /392	N/A	Registry	Outcome	Patient Safety	HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation This measure is reported as four rates stratified by age and gender: • Reporting Age Criteria 1: Females less than 65 years of age • Reporting Age Criteria 2: Males less than 65 years of age • Reporting Age Criteria 3: Females 65 years of age and older • Reporting Age Criteria 4: Males 65 years of age and older	The Heart Rhythm Society
!	N/A/ 393	N/A	Registry	Outcome	Patient Safety	HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision Infection rate following CIED device implantation, replacement, or revision	The Heart Rhythm Society

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
4. Gastroenterology							
§	0034 /113	130v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Colorectal Cancer Screening Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer	National Committee for Quality Assurance
§ !!	0659 /185	N/A	Claims, Registry	Process	Communication and Care Coordination	Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy	American Medical Association-Physician Consortium for Performance Improvement American / Gastroenterological Association/ 'American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
§ !!	0658 /320	N/A	Claims, Registry	Process	Communication and Care Coordination	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report	American Medical Association-Physician Consortium for Performance Improvement / American Gastroenterological Association/ 'American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
§ !	N/A/ 343	N/A	Registry	Outcome	Effective Clinical Care	Screening Colonoscopy Adenoma Detection Rate Measure The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy	American College of Gastroenterology / American Gastroenterological Association/ 'American Society for Gastrointestinal Endoscopy

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
4. Gastroenterology							
!	N/A/ 390	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
§	N/A/ 401	N/A	Registry	Process	Effective Clinical Care	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
§ !!	N/A/ 439	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Age Appropriate Screening Colonoscopy The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31	American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
5. Dermatology							
!	0650/ 137	N/A	Registry	Structure	Communication and Care Coordination	Melanoma: Continuity of Care – Recall System Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 138	N/A	Registry	Process	Communication and Care Coordination	Melanoma: Coordination of Care Percentage of patients visits, regardless of age, with a new occurrence of melanoma, who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
!!	0562/ 224	N/A	Registry	Process	Efficiency and Cost Reduction	Melanoma: Overutilization of Imaging Studies in Melanoma Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 265	N/A	Registry	Process	Communication and Care Coordination	Biopsy Follow-Up Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology
	N/A/ 337	N/A	Registry	Process	Effective Clinical Care	Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
5. Dermatology							
!	N/A/ 410		Claims, Registry	Outcome	Person and Caregiver Centered Experience and Outcomes	Psoriasis: Clinical Response to Oral Systemic or Biologic Medications Percentage of psoriasis patients receiving oral systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
6. Emergency Medicine							
* !!	N/A/ 066	146v4	Registry, EHR	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	National Committee for Quality Assurance
!!	0653/ 091	N/A	Claims, Registry	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology-Head and Neck Surgery
!!	0654/ 093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
6. Emergency Medicine							
§ !!	0058/ 116	N/A	Registry	Process	Efficiency and Cost Reduction	Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance
	0651/ 254	N/A	Claims, Registry	Process	Effective Clinical Care	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location	American College of Emergency Physicians
	N/A/ 255	N/A	Claims, Registry	Process	Effective Clinical Care	Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED)	American College of Emergency Physicians
	N/A/ 414	N/A	Registry	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
!	N/A/ 415	N/A	Claims, Registry	Efficiency	Efficiency and Cost Reduction	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
6. Emergency Medicine							
!!	N/A/ 416	N/A	Claims, Registry	Efficiency	Efficiency and Cost Reduction	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network prediction rules for traumatic brain injury	American College of Emergency Physicians

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
7. General Practice/Family Medicine							
* § !	0059 /001	122v4	Claims, Registry, EHR	Intermediate Outcome	Effective Clinical Care	Diabetes: Hemoglobin A1c Poor Control Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	National Committee for Quality Assurance
§	0081 /005	135v4	Registry, EHR	Process	Effective Clinical Care	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD) Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	American Medical Association-Physician Consortium for Performance/ American College of Cardiology Foundation/American Heart Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
7. General Practice/Family Medicine							
	105/ 009	128v4	EHR	Process	Effective Clinical Care	Anti-Depressant Medication Management Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months)	National Committee for Quality Assurance/American Heart Association
!	N/A/ 050	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement
!!	0069 /065	154v4	Registry, EHR	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI) Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode	National Committee for Quality Assurance
* !!	N/A/ 066	146v4	Registry, EHR	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	National Committee for Quality Assurance
!!	0654 /093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery
!	N/A/ 109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
7. General Practice/Family Medicine							
* §	2372 /112	125v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Breast Cancer Screening Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer	National Committee for Quality Assurance
§	0034 /113	130v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Colorectal Cancer Screening Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer	National Committee for Quality Assurance
§ !!	0058 /116	N/A	Registry	Process	Efficiency and Cost Reduction	Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance
§	0055 /117	131v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Diabetes: Eye Exam Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period	National Committee for Quality Assurance
*	0418 /134	2v5	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
!	0101 /154	N/A	Claims, Registry	Process	Patient Safety	Falls: Risk Assessment Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!	0101 /155	N/A	Claims, Registry	Process	Communication and Care Coordination	Falls: Plan of Care Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance/ 'American Medical Association-

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
7. General Practice/Family Medicine							
							Physician Consortium for Performance Improvement
!	NA/ 181	N/A	Claims, Registry	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
* §	0068 /204	164v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period	National Committee for Quality Assurance
§ !!	0052 /312	166v5	Web Interface, EHR	Process	Efficiency and Cost Reduction	Use of Imaging Studies for Low Back Pain Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis	National Committee for Quality Assurance
§	1525 /326	N/A	Claims, Registry	Process	Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
				7. General Practice/Family Medicine			
!!	N/A/ 331	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse) Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 332	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
	N/A/ 337	N/A	Registry	Process	Effective Clinical Care	Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
* § !	2082 /338	N/A	Registry	Outcome	Effective Clinical Care	HIV Viral Load Suppression The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year	Health Resources and Services Administration

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
7. General Practice/Family Medicine							
!	N/A/ 342	N/A	Registry	Outcome	Person and Caregiver-Centered Experience and Outcomes	Pain Brought Under Control Within 48 Hours Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours	National Hospice and Palliative Care Organization
	N/A/ 387	N/A	Registry	Process	Effective Clinical Care	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period	American Medical Association-Physician Consortium for Performance Improvement
	1407 /394	N/A	Registry	Process	Community/ Population Health	Immunizations for Adolescents The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday	National Committee for Quality Assurance
!	N/A/ 398	N/A	Registry	Outcome	Effective Clinical Care	Optimal Asthma Control Patients ages 5-50 (pediatrics ages 5-17) whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools	Minnesota Community Measurement
§	N/A/ 400	N/A	Registry	Process	Effective Clinical Care	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection	American Medical Association-Physician Consortium for Performance Improvement
§	N/A/ 401	N/A	Registry	Process	Effective Clinical Care	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
7. General Practice/Family Medicine							
	N/A/ 408	N/A	Registry	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 412	N/A	Registry	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 414	N/A	Registry	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
	0053 /418	N/A	Claims, Registry	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
	N/A/ 438	N/A	Web Interface, Registry	Process	Effective Clinical Care	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
7. General Practice/Family Medicine							
						• Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Pennsylvania

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
8. Internal Medicine							
* § !	0059 /001	122v4	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	Diabetes: Hemoglobin A1c Poor Control Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	National Committee for Quality Assurance
§	0081 /005	135v4	Registry, EHR	Process	Effective Clinical Care	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD) Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
8. Internal Medicine							
	105/ 009	128v4	EHR	Process	Effective Clinical Care	Anti-Depressant Medication Management Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months)	National Committee for Quality Assurance/American Heart Association
!	N/A/ 050	N/A	Claims, Registry	Process	Person and Caregiver Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 109	N/A	Claims, Registry	Process	Person and Caregiver Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
* §	2372 /112	125v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Breast Cancer Screening Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer	National Committee for Quality Assurance
§	0034 /113	130v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Colorectal Cancer Screening Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer	National Committee for Quality Assurance
§ !!	0058 /116	N/A	Registry	Process	Efficiency and Cost Reduction	Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
8. Internal Medicine							
§	0055 /117	131v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Diabetes: Eye Exam Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period	National Committee for Quality Assurance
*	0418 /134	2v5	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
!	0101 /154	N/A	Claims, Registry	Process	Patient Safety	Falls: Risk Assessment Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!	0101 /155	N/A	Claims, Registry	Process	Communication and Care Coordination	Falls: Plan of Care Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
* §	0056 /163	123v4	EHR	Process	Effective Clinical Care	Comprehensive Diabetes Care: Foot Exam The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
8. Internal Medicine							
!	N/A/ 181	N/A	Claims, Registry	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
* §	0068 /204	164v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period	National Committee for Quality Assurance
§	1525 /326	N/A	Claims, Registry	Process	Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
!!	N/A/ 331	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse) Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 332	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
8. Internal Medicine							
!!	N/A/ 333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
	N/A/ 387	N/A	Registry	Process	Effective Clinical Care	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period	American Medical Association-Physician Consortium for Performance Improvement
§	N/A/ 400	N/A	Registry	Process	Effective Clinical Care	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection	American Medical Association-Physician Consortium for Performance Improvement
§	N/A/ 401	N/A	Registry	Process	Effective Clinical Care	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67814)	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
8. Internal Medicine							
	N/A/ 408	N/A	Registry	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 412	N/A	Registry	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 414	N/A	Registry	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
	0053 /418	N/A	Claims, Registry	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
9. Obstetrics/Gynecology							
	N/A/ 048	N/A	Claims, Registry	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 050	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 265	N/A	Registry	Process	Communication and Care Coordination	Biopsy Follow-Up Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology
	0053 /418	N/A	Claims, Registry	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
9. Obstetrics/Gynecology							
!	2063 /422	N/A	Claims, Registry	Process	Patient Safety	Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse	American Urogynecologic Society
!	N/A/ 432	N/A	Registry	Outcome	Patient Safety	Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery	American Urogynecologic Society
!	N/A/ 433	N/A	Registry	Outcome	Patient Safety	Proportion of Patients Sustaining a Major Viscus Injury at the Time of Any Pelvic Organ Prolapse Repair Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by perforation of a major viscus at the time of index surgery that is recognized intraoperative or within 1 month after surgery	American Urogynecologic Society
!	N/A/ 434	N/A	Registry	Outcome	Patient Safety	Proportion of Patients Sustaining A Ureter Injury at the Time of any Pelvic Organ Prolapse Repair Percentage of patients undergoing a pelvic organ prolapse repair who sustain an injury to the ureter recognized either during or within 1 month after surgery	American Urogynecologic Society
* §	0032 /309	124v4	EHR	Process	Effective Clinical Care	Cervical Cancer Screening Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years	National Committee for Quality Assurance
+ §	1395 / New	N/A	Registry	Process	Community/ Population Health	Chlamydia Screening and Follow-up The percentage of female adolescents 18 years of age who had a chlamydia screening test with proper follow-up	National Committee for Quality Assurance
* §	2372 /112	125v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Breast Cancer Screening Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						9. Obstetrics/Gynecology	
+ § !	0567 / New	N/A	Registry	Process	Patient Safety	Appropriate Work Up Prior to Endometrial Ablation Procedure To ensure that all women have endometrial sampling performed before undergoing an endometrial ablation	Health Benchmarks-IMS Health
+ § !!	N/A/ New	N/A	Registry	Process	Patient Safety	Non-recommended Cervical Cancer Screening in Adolescent Females The percentage of adolescent females 16–20 years of age unnecessarily screened for cervical cancer	National Committee for Quality Assurance
	0033 /310	153v4	EHR	Process	Community/ Population Health	Chlamydia Screening for Women Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period	National Committee for Quality Assurance

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						10. Ophthalmology	
	0086 /012	143v4	Claims, Registry, EHR	Process	Effective Clinical Care	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
10. Ophthalmology							
	0087 /014	N/A	Claims, Registry	Process	Effective Clinical Care	Age-Related Macular Degeneration (AMD): Dilated Macular Examination Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months	American Academy of Ophthalmology
	0088 /018	167v4	EHR	Process	Effective Clinical Care	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0089 /019	142v4	Claims, Registry, EHR	Process	Communication and Care Coordination	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
§	0055 /117	131v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Diabetes: Eye Exam Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period	National Committee for Quality Assurance
	0566 /140	N/A	Claims, Registry	Process	Effective Clinical Care	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD	American Academy of Ophthalmology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
10. Ophthalmology							
!	0563 /141	N/A	Claims, Registry	Outcome	Communication and Care Coordination	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre- intervention level, a plan of care was documented within 12 months	American Academy of Ophthalmology
!	0565 /191	133v4	Registry, EHR	Outcome	Effective Clinical Care	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0564 /192	132v4	Registry, EHR	Outcome	Patient Safety	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	1536 /303	N/A	Registry	Outcome	Person Caregiver-Centered Experience and Outcomes	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey	American Academy of Ophthalmology
!	N/A/ 304	N/A	Registry	Outcome	Person Caregiver-Centered Experience and Outcomes	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	American Academy of Ophthalmology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
10. Ophthalmology							
!	N/A/ 384	N/A	Registry	Outcome	Effective Clinical Care	Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
!	N/A/ 385	N/A	Registry	Outcome	Effective Clinical Care	Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye	American Academy of Ophthalmology/ The Australian Council on Healthcare Standards
!	N/A/ 388	N/A	Registry	Outcome	Patient Safety	Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy	American Academy of Ophthalmology/ American College of Healthcare Sciences
!	N/A/ 389	N/A	Registry	Outcome	Effective Clinical Care	Cataract Surgery: Difference Between Planned and Final Refraction Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology/ American College of Healthcare Sciences

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
11. Orthopedic Surgery							
!!	0268/ 021	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0239/ 023	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	N/A/ 109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
	N/A/ 178	N/A	Registry, Measures Group	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Functional Status Assessment Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months	American College of Rheumatology
*	N/A/ 179	N/A	Registry	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months	American College of Rheumatology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
11. Orthopedic Surgery							
*	N/A/ 180	N/A	Registry	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Glucocorticoid Management Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	American College of Rheumatology
§ !!	0052/ 312	166v5	Web Interface, EHR	Process	Efficiency and Cost Reduction	Use of Imaging Studies for Low Back Pain Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis	National Committee for Quality Assurance
* !	N/A/ 350	N/A	Registry	Process	Communication and Care Coordination	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. Nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure	American Association of Hip and Knee Surgeons
* !	N/A/ 351	N/A	Registry	Process	Patient Safety	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke)	American Association of Hip and Knee Surgeons
* !	N/A/ 352	N/A	Registry	Process	Patient Safety	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet Percentage of patients regardless of age or gender undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	American Association of Hip and Knee Surgeons
* !	N/A/ 353	N/A	Registry	Process	Patient Safety	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report Percentage of patients regardless of age or gender undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant	American Association of Hip and Knee Surgeons

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
11. Orthopedic Surgery							
!	N/A/ 358	N/A	Registry, Measures Group	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American Association of Hip and Knee Surgeons
* !	N/A/ 375	N/A	Measures Group	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessment for Total Knee Replacement Percentage of patients 18 years of age and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported functional status assessments	Centers for Medicare & Medicaid Services/ National Committee for Quality Assurance
* !	N/A/ 376	N/A	EHR	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessment for Total Hip Replacement Percentage of patients 18 years of age and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments	Centers for Medicare & Medicaid Services/ National Committee for Quality Assurance

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
12. Otolaryngology							
!!	0268/ 021	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation	American Medical Association-Physician Consortium for Performance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description*	Measure Steward
12. Otolaryngology							
						cephalosporin for antimicrobial prophylaxis	Improvement/ National Committee for Quality Assurance
!	0239/ 023	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!!	0653/ 091	N/A	Claims, Registry	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	'American Academy of Otolaryngology-Head and Neck Surgery
!!	0654/ 093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 331	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse) Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 332	N/A	Registry	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A/ 333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
12. Otolaryngology							
!!	N/A/ 334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse) Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
* !	N/A/ 357	N/A	Registry	Outcome	Effective Clinical Care	Surgical Site Infection (SSI) Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A/ 358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
13. Pathology							
	0391 /099	N/A	Claims, Registry	Process	Effective Clinical Care	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade	College of American Pathologists

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						13. Pathology	
	0392 /100	N/A	Claims, Registry	Process	Effective Clinical Care	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	College of American Pathologists
	1854 /249	N/A	Claims, Registry	Structure	Effective Clinical Care	Barrett's Esophagus Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia	College of American Pathologists
§	1853 /250	N/A	Claims, Registry	Structure	Effective Clinical Care	Radical Prostatectomy Pathology Reporting Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status	College of American Pathologists
	1855 /251	N/A	Claims, Registry	Structure	Effective Clinical Care	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	College of American Pathologists
!	N/A/ 395	N/A	Claims, Registry	Process	Communication and Care Coordination	Lung Cancer Reporting (Biopsy/Cytology Specimens) Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report	College of American Pathologists
!	N/A/ 396	N/A	Claims, Registry	Process	Communication and Care Coordination	Lung Cancer Reporting (Resection Specimens) Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type	College of American Pathologists
!	N/A/ 397	N/A	Claims, Registry	Process	Communication and Care Coordination	Melanoma Reporting Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate	College of American Pathologists

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
13. Pathology							
Cross-cutting measure requirement: In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.							

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
14. Pediatrics							
!!	0069 /065	154v4	Registry, EHR	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI) Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
* !!	N/A/ 066	146v4	Registry, EHR	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
!!	0653 /091	N/A	Claims, Registry	Process	Effective Clinical Care	Acute Otitis External (AOE): Topical Therapy Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology-Head and Neck Surgery
!!	0654 / 093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery
	0041 /110	147v5	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	Preventive Care and Screening: Influenza Immunization Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
14. Pediatrics							
*	0418 /134	2v5	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services/ 'Mathematica/ Quality Insights of Pennsylvania
* §	0405 /160	52v4	EHR	Process	Effective Clinical Care	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis	National Committee for Quality Assurance
§	0409 /205	N/A	Registry	Process	Effective Clinical Care	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
	0024 /239	155v4	EHR	Process	Community / Population Health	Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity	National Committee for Quality Assurance
	0038 /240	117v4	EHR	Process	Community /Population Health	Childhood Immunization Status Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
14. Pediatrics							
Cross-cutting measure requirement: In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.							

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
15. Physical Medicine							
!	N/A/ 109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
!	0420 /131	N/A	Claims, Registry	Process	Communication and Care Coordination	Pain Assessment and Follow-Up Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
!	2624 /182	N/A	Claims, Registry	Process	Communication and Care Coordination	Functional Outcome Assessment Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
§ !!	0052 /312	166v5	Web Interface, EHR	Process	Efficiency and Cost Reduction	Use of Imaging Studies for Low Back Pain Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						15. Physical Medicine	
	N/A/ 408	N/A	Registry	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 412	N/A	Registry	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 414	N/A	Registry	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						16. Plastic Surgery	
!!	0268 /021	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0239 /023	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose	American Medical Association-Physician Consortium for Performance Improvement/

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
16. Plastic Surgery							
						Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	National Committee for Quality Assurance
!	N/A/ 358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
17. Preventive Medicine							
* § !	0059 /001	122v4	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	Diabetes: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%) Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
17. Preventive Medicine							
!	0045 /024	N/A	Claims, Registry	Process	Communication and Care Coordination	Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
	0046 /039	N/A	Claims, Registry	Process	Effective Clinical Care	Screening for Osteoporosis for Women Aged 65-85 Years of Age Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
	N/A/ 048	N/A	Claims, Registry	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
	0041 /110	147v5	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	Preventive Care and Screening: Influenza Immunization Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	American Medical Association-Physician Consortium for Performance Improvement
	0043 /111	127v4	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	Pneumonia Vaccination Status for Older Adults Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						17. Preventive Medicine	
* §	2372 /112	125v4	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	Breast Cancer Screening Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer	National Committee for Quality Assurance

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						18. Neurology	
	0325 /032	N/A	Claims, Registry	Process	Effective Clinical Care	Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an antithrombotic at discharge	American Academy of Neurology
*	1814 /268	N/A	Claims, Registry	Process	Effective Clinical Care	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year	American Academy of Neurology
	N/A/ 281	149v4	EHR	Process	Effective Clinical Care	Dementia: Cognitive Assessment Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period	American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
18. Neurology							
*	N/A/ 282	N/A	Registry	Process	Effective Clinical Care	Dementia: Functional Status Assessment Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period	American Academy of Neurology/ American Psychiatric Association
*	N/A/ 283	N/A	Registry	Process	Effective Clinical Care	Dementia: Neuropsychiatric Symptom Assessment Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	American Academy of Neurology/ American Psychiatric Association
*	N/A/ 284	N/A	Registry	Process	Effective Clinical Care	Dementia: Management of Neuropsychiatric Symptoms Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	American Academy of Neurology/ American Psychiatric Association
* !	N/A/ 286	N/A	Registry	Process	Patient Safety	Dementia: Counseling Regarding Safety Concerns Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	American Academy of Neurology/ American Psychiatric Association
* !	N/A/ 288	N/A	Registry	Process	Communication and Care Coordination	Dementia: Caregiver Education and Support Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	American Academy of Neurology/ American Psychiatric Association
*	N/A/ 290	N/A	Registry	Process	Effective Clinical Care	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually	American Academy of Neurology
*	N/A/ 291	N/A	Registry	Process	Effective Clinical Care	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually	American Academy of Neurology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
						18. Neurology	
* !	N/A/ 293	N/A	Registry	Process	Communication and Care Coordination	Parkinson's Disease: Rehabilitative Therapy Options All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually	American Academy of Neurology
* !	N/A/ 294	N/A	Registry	Process	Communication and Care Coordination	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	American Academy of Neurology
!	N/A/ 386	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive ventilation, hospice) at least once annually	American Academy of Neurology
	N/A/ 408	N/A	Registry	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 412	N/A	Registry	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A/ 414	N/A	Registry	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
!!	N/A/ 419	N/A	Claims, Registry	Efficiency	Efficiency and Cost Reduction	Overuse Of Neuroimaging For Patients With Primary Headache And A Normal Neurological Examination Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered	American Academy of Neurology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
18. Neurology							
!	N/A/ 435	N/A	Claims, Registry	Outcome	Effective Clinical Care	Quality Of Life Assessment For Patients With Primary Headache Disorders Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved	American Academy of Neurology
Cross-cutting measure requirement: In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.							

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
19. Mental/Behavioral Health							
	105/ 009	128v4	EHR	Process	Effective Clinical Care	Anti-Depressant Medication Management Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months)	National Committee for Quality Assurance/American Heart Association
*	0418 /134	N/A	Claims, Web Interface, Registry, EHR, Measures Groups	Process	Community /Population Health	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
19. Mental/Behavioral Health							
!	N/A/ 181	N/A	Claims, Registry	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
	N/A/ 281	149v4	EHR	Process	Effective Clinical Care	Dementia: Cognitive Assessment Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period	American Medical Association-Physician Consortium for Performance Improvement
*	N/A/ 282	N/A	Registry	Process	Effective Clinical Care	Dementia: Functional Status Assessment Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period	American Academy of Neurology/ American Psychiatric Association
*	N/A/ 283	N/A	Registry	Process	Effective Clinical Care	Dementia: Neuropsychiatric Symptom Assessment Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	American Academy of Neurology/ American Psychiatric Association
*	N/A/ 284	N/A	Registry	Process	Effective Clinical Care	Dementia: Management of Neuropsychiatric Symptoms Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	American Academy of Neurology/ American Psychiatric Association
* !	N/A/ 286	N/A	Registry	Process	Patient Safety	Dementia: Counseling Regarding Safety Concerns Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	American Academy of Neurology/ American Psychiatric Association
* !	N/A/ 288	N/A	Registry	Process	Communication and Care Coordination	Dementia: Caregiver Education and Support Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	American Academy of Neurology/ American Psychiatric Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
19. Mental/Behavioral Health							
!	N/A/ 325	N/A	Registry	Process	Communication/ Care Coordination	Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition	American Psychiatric Association/ American Medical Association-Physician Consortium for Performance Improvement
!	1879 /383	N/A	Registry	Intermediate Outcome	Patient Safety	Adherence to Antipsychotic Medications for Individuals with Schizophrenia Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months)	Health Services Advisory Group/ Centers for Medicare & Medicaid Services
!	0576 /391	N/A	Registry	Process	Communication/ Care Coordination	Follow-up After Hospitalization for Mental Illness (FUH) The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported: - The percentage of discharges for which the patient received follow-up within 30 days of discharge - The percentage of discharges for which the patient received follow-up within 7 days of discharge	National Committee for Quality Assurance

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
20. Radiology							
20a. Diagnostic Radiology							
!!	N/A/ 145	N/A	Registry	Process	Patient Safety	Radiology: Exposure Time Reported for Procedures Using Fluoroscopy Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available)	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
!	0508 / 146	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening Percentage of final reports for screening mammograms that are classified as "probably benign"	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 147	N/A	Claims, Registry	Process	Communication and Care Coordination	Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed	American Medical Association-Physician Consortium for Performance Improvement/ Society of Nuclear Medicine and Molecular Imaging
	0507 / 195	N/A	Claims, Registry	Process	Effective Clinical Care	Radiology: Stenosis Measurement in Carotid Imaging Reports Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
						20. Radiology	
!	0509 /225	N/A	Claims, Registry	Structure	Communication and Care Coordination	Radiology: Reminder System for Screening Mammograms Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
* !	N/A/ 359	N/A	Registry	Process	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems	American College of Radiology
* !!	N/A/ 360	N/A	Registry	Process	Patient Safety	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
* !	N/A/ 361	N/A	Registry	Structure	Patient Safety	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	American College of Radiology
* !	N/A/ 362	N/A	Registry	Structure	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	American College of Radiology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
						20. Radiology	
						This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74667)	
* !	N/A/ 363	N/A	Registry	Process	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	American College of Radiology
* !!	N/A/ 364	N/A	Registry	Process	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors	American College of Radiology
	N/A/ 405	N/A	Claims, Registry	Process	Effective Clinical Care	Appropriate Follow-up Imaging for Incidental Abdominal Lesions Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: • Liver lesion ≤ 0.5 cm • Cystic kidney lesion < 1.0 cm • Adrenal lesion ≤ 1.0 cm	American College of Radiology
!!	N/A/ 406	N/A	Claims, Registry	Process	Effective Clinical Care	Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients Percentage of final reports for computed tomography (CT) or magnetic resonance imaging (MRI) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended	American College of Radiology
	N/A/ 436	N/A	Claims, Registry	Process	Effective Clinical Care	Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques Percentage of final reports for patients aged 18 years and	American College of Radiology/ American

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
20. Radiology							
						older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Use of iterative reconstruction technique	Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
20b. Interventional Radiology							
!	N/A/ 259	N/A	Registry	Outcome	Patient Safety	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2) Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	Society for Vascular Surgeons
!	N/A/ 265	N/A	Registry	Process	Communication and Care Coordination	Biopsy Follow-Up Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology
!	N/A/ 344	N/A	Registry	Outcome	Effective Clinical Care	Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2	Society for Vascular Surgeons
!	N/A/ 345	N/A	Registry	Outcome	Effective Clinical Care	Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital	Society for Vascular Surgeons
20c. Radiation Oncology							
* § !!	0389 /102	129v5	Registry, EHR	Process	Efficiency and Cost Reduction	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of	American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
20. Radiology							
						prostate cancer	
§ !	0384 /143	157v4	Registry, EHR	Process	Person and Caregiver Centered Experience and Outcome	Oncology: Medical and Radiation – Pain Intensity Quantified Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	American Medical Association-Physician Consortium for Performance Improvement
!	0383 /144	N/A	Registry	Process	Person and Caregiver Centered Experience and Outcome	Oncology: Medical and Radiation – Plan of Care for Pain Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	American Society of Clinical Oncology
!!	0382 /156	N/A	Claims, Registry	Process	Patient Safety	Oncology: Radiation Dose Limits to Normal Tissues Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues	American Society for Radiation Oncology

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
21. Surgery							
21a. Vascular Surgery							
!	N/A/ 258	N/A	Registry	Outcome	Patient Safety	Rate of Open Elective Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7) Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)	Society for Vascular Surgeons
!	N/A/ 259	N/A	Registry	Outcome	Patient Safety	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2) Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	Society for Vascular Surgeons
!	N/A/ 260	N/A	Registry	Outcome	Patient Safety	Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2) Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2)	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	N/A/ 344	N/A	Registry	Outcome	Effective Clinical Care	Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2	Society for Vascular Surgeons
!	N/A/ 345	N/A	Registry	Outcome	Effective Clinical Care	Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital	Society for Vascular Surgeons
!	1534 /347	N/A	Registry	Outcome	Patient Safety	Rate of Endovascular Aneurysm Repair (EVAR of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital	American Medical Association-Physician Consortium for Performance Improvement/

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
21. Surgery							
							National Committee for Quality Assurance
21b. General Surgery							
!!	0268 /021	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalasporin Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, which had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0271 /022	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures) Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
!	0239 /023	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
* !	N/A/ 354	N/A	Registry	Outcome	Patient Safety	Anastomotic Leak Intervention Percentage patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery	American College of Surgeons

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
21. Surgery							
* !	N/A/ 355	N/A	Registry	Outcome	Patient Safety	Unplanned Reoperation within the 30 Day Postoperative Period Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period	American College of Surgeons
* !	N/A/ 356	N/A	Registry	Outcome	Effective Clinical Care	Unplanned Hospital Readmission within 30 Days of Principal Procedure Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure	American College of Surgeons
* !	N/A/ 357	N/A	Registry	Outcome	Effective Clinical Care	Surgical Site Infection (SSI) Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A/ 358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
22. Thoracic Surgery							
!!	0268 /021	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Medical Association-Physician Consortium for Performance/ National Committee for Quality Assurance
!	0239 /023	N/A	Claims, Registry	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Medical Association-Physician Consortium for Performance/ National Committee for Quality Assurance
!	0129 /164	N/A	Registry	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Prolonged Intubation Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours	American Thoracic Society
* !	0130 /165	N/A	Registry	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention	American Thoracic Society
* !	0131 /166	N/A	Registry	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Stroke Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	American Thoracic Society

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
22. Thoracic Surgery							
* !	0114 /167	N/A	Registry	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	American Thoracic Society
* !	0115 /168	N/A	Registry	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	Society of Thoracic Surgeons
* !	N/A/ 357	N/A	Registry	Outcome	Effective Clinical Care	Surgical Site Infection (SSI) Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A/ 358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

Cross-cutting measure requirement:

In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
23. Urology							
	N/A/ 048	N/A	Claims, Registry	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
!	N/A/ 050	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Assessment of Presence or Absence Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
* § !!	0389/ 102	129v5	Registry, EHR	Process	Efficiency and Cost Reduction	Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	American Medical Association-Physician Consortium for Performance Improvement
	0390/ 104	N/A	Registry	Process	Effective Clinical Care	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or very High Risk Prostate Cancer Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist	American Medical Association-Physician Consortium for Performance Improvement/ American Urological Association Education and Research

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
23. Urology							
!	N/A/ 265	N/A	Registry	Process	Communication and Care Coordination	Biopsy Follow-Up Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology
* !	N/A/ 357	N/A	Registry	Outcome	Effective Clinical Care	Surgical Site Infection (SSI) Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A/ 358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

Cross-cutting measure requirement:
In addition to reporting measures within the specialty measure set, MIPS eligible clinicians that have face-to-face encounters and are considered patient-facing providers, must report at least one cross-cutting measure from the cross-cutting measures list in Table C.

TABLE F: 2016 PQRS Measures Proposed for Removal for MIPS Reporting in 2017

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
	N/A/ 002	163v4	EHR	Effective Clinical Care	Diabetes: Low Density Lipoprotein (LDL-C) Control (<100 mg/dL) Percentage of patients 18–75 years of age with diabetes whose LDL-C was adequately controlled (< 100 mg/dL) during the measurement period **Rationale:** This measure no longer reflects evidence. CMS proposes removal of measure because it no longer reflects clinical guidelines and evidence. Clinical guidelines are better represented by PQRS # 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[v]	Measure Steward
!	0271/ 022	N/A	Claims, Registry	Patient Safety	Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures) Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time **Rationale:** CMS proposes to remove this measure because it is considered low bar and is part of standard clinical practice. There is no significant performance gap for this measure as indicated by high performance rates. Removing this measure will not significantly impact surgeons' ability to report.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
	NA/ 041	NA		Effective Clinical Care	Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older Percentage of patients aged 50 years and older with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months Rationale: The measure steward will no longer support stewardship of this measure. Measures implemented in the quality measure program are required to be updated annually by the measure steward. Since the measure steward has removed its support to update this measure in 2017, CMS proposes removal of the measure.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
	0047/ 053	N/A	Registry, Measures Group	Effective Clinical Care	Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting Percentage of patients aged 5 years and older with a diagnosis of persistent asthma who were prescribed long-term control medication **Rationale:** CMS proposes removal of this measure because it is being replaced by NQF 1799: Medication Management for People with Asthma. NQF #1799 is a measure included on collaborative core set.	American Academy of Allergy, Asthma, and Immunology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
	0090/ 054	N/A	Claims, Registry	Effective Clinical Care	Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead electrocardiogram (ECG) performed **Rationale:** CMS proposes to remove this measure because it is considered low bar and is part of standard clinical practice. There is no significant performance gap for this measure as indicated by high performance rates. Removal of this measure does not impact the number of adequate measures for Emergency Department Physicians.	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
	0387/ 071	CMS140v4	Claims, Registry, EHR, Measures Group	Effective Clinical Care	Breast Cancer: Hormonal Therapy for Stage IC -IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period **Rationale:** Due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure as it is similar to a core measure. This measure is closely related to one of the core measures covered under the Core Measure Collaborative and is not included in the core measure set. Additionally, the clinical performance identified with this measure can be addressed by the measures within the core measure set.	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Clinical Oncology/ National Comprehensive Cancer Network
	0385 /072	CMS141v5	Claims, Registry, EHR, Measures Group	Effective Clinical Care	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period **Rationale:** Due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure as it is similar to a core measure. This measure is closely related to one of the core measures covered under the Core Measure Collaborative and is not included in the core measure set. Additionally, the clinical performance identified with this measure can be addressed by the measures within the core measure set.	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Clinical Oncology/ National Comprehensive Cancer Network

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
	0395/ 084	N/A	Measures Group	Effective Clinical Care	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV) ribonucleic acid (RNA) testing was performed within 12 months prior to initiation of antiviral treatment **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Medical Association-Physician Consortium for Performance Improvement /American Gastroenterological Association
	0396/ 085	N/A	Measures Group	Effective Clinical Care	Hepatitis C: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Medical Association-Physician Consortium for Performance Improvement /American Gastroenterological Association
	0398/ 087	N/A	Measures Group	Effective Clinical Care	Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) ribonucleic acid (RNA) testing was performed between 4-12 weeks after the initiation of antiviral treatment **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Academy of Neurology/ American Psychiatric Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
	0054/ 108	N/A	Measures Group	Effective Clinical Care	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy Percentage of patients aged 18 years and older who were diagnosed with rheumatoid arthritis and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD) **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	National Committee for Quality Assurance
	N/A/ 121	N/A	Registry, Measures Group	Effective Clinical Care	Adult Kidney Disease: Laboratory Testing (Lipid Profile) Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period **Rationale:** CMS proposes removal of this measure because it is considered a low bar measure and is part of standard clinical practice. There is no significant performance gap for this measure as indicated by high performance rates.	Renal Physicians Association
	0399/ 183	N/A	Measures Group	Community/ Population Health	Hepatitis C: Hepatitis A Vaccination Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure, this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
	N/A/ 241	182v5	EHR	Effective Clinical Care	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (< 100 mg/dL) Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL)	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
					Rationale: This measure no longer reflects evidence. CMS proposes removal of measure because it no longer reflects clinical guidelines and evidence. Clinical guidelines are better represented by PQRS # 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	
	N/A/ 242	N/A	Measures Group	Effective Clinical Care	Coronary Artery Disease (CAD): Symptom Management Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
	N/A/ 270	N/A	Registry, Measures Group	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy within the last twelve months **Rationale:** Due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure. This measure is related to one of the conditions covered under the Core Measure Collaborative but is not included in the core measure set. The clinical performance identified with this measure can be addressed by the measures within the core measure set.	American Gastroenterological Association
	N/A/ 274	N/A	Registry, Measures Group	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) for whom a tuberculosis (TB) screening was performed and results interpreted within six months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy **Rationale:** Due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure. This measure is related to one of the conditions covered under the Core Measure Collaborative but is not included in the core	American Gastroenterological Association

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
					measure set. The clinical performance identified with this measure can be addressed by the measures within the core measure set.	
	N/A/ 280	N/A	Measures Group	Effective Clinical Care	Dementia: Staging of Dementia Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Academy of Neurology/ American Psychiatric Association
	N/A/ 287	N/A	Measures Group	Effective Clinical Care	Dementia: Counseling Regarding Risks of Driving Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
	N/A/ 289	N/A	Measures Group	Effective Clinical Care	Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Academy of Neurology

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
	N/A/ 292	N/A	Measures Group	Effective Clinical Care	Parkinson's Disease: Querying about Sleep Disturbances All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually **Rationale:** This measure was previously a part of a Measures Group and was reportable as a measures group only. To align with the proposed MIPS policy of removing Measures Group as a reporting option, this measure will no longer be reportable as part of a measure group. As an individual measure this measure is considered low-bar and not robust enough to stand alone. CMS proposes to remove this measure because it is considered low-bar as an individual measure and is standard clinical practice.	American Academy of Neurology
	0036/ 311	126v4	EHR	Effective Clinical Care	Use of Appropriate Medications for Asthma Percentage of patients 5-64 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement period **Rationale:** This measure has a high performance rate and shows little variation in care. CMS proposes removal of measure because it has a high performance rate and is clinically close to another measure that is being proposed, NQF 1799: Medication Management for people with Asthma.	National Committee for Quality Assurance
	2083/ 339	N/A	Measures Group	Effective Clinical Care	Prescription of HIV Antiretroviral Therapy Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year **Rationale:** Due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure. This measure is related to one of the conditions covered under the Core Measure Collaborative but is not included in the core measure set. The clinical performance identified with this measure can be addressed by the measures within the core measure set.	Health Resources and Services Administration
	N/A/ 365	148v4	EHR	Effective Clinical Care	Hemoglobin A1c Test for Pediatric Patients Percentage of patients 5-17 years of age with diabetes with a HbA1c test during the measurement period **Rationale:** CMS proposes removal of this measure because the measure owner is no longer supporting implementation. Additionally, the evidence for this measure is no longer supported by clinical experts and guidance.	National Committee for Quality Assurance

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
	N/A/ 368	62v4	EHR	Effective Clinical Care	HIV/AIDS: Medical Visit Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 90 days between each visit **Rationale:** According to clinical experts, this measure no longer reflects the evidence. CMS proposes removal of measure because it no longer reflects clinical guidelines and evidence.	National Committee for Quality Assurance
!	N/A/ 380	CMS179v4	EHR	Patient Safety	ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range Average percentage of time in which patients aged 18 and older with atrial fibrillation who are on chronic warfarin therapy have International Normalized Ratio (INR) test results within the therapeutic range (i.e., TTR) during the measurement period **Rationale:** Since its implementation, this measure has had difficulty with feasibility. CMS proposes this measure be removed because it is not technically feasible to implement.	Centers for Medicare & Medicaid Services/ National Committee for Quality Assurance
	N/A/ 381	77v4	EHR	Effective Clinical Care	HIV/AIDS: RNA Control for Patients with HIV Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL. **Rationale:** According to clinical experts, this measure no longer reflects the evidence. CMS proposes removal of measure because it no longer reflects clinical guidelines and evidence.	Centers for Medicare & Medicaid Services/ National Committee for Quality Assurance
	2452/ 399	N/A	Registry	Effective Clinical Care	Post-Procedural Optimal Medical Therapy Composite (Percutaneous Coronary Intervention) Percentage of patients aged 18 years and older for whom PCI is performed who are prescribed optimal medical therapy at discharge **Rationale:** The measure steward will no longer support stewardship of this measure. Measures implemented in the quality measure program are required to be updated annually by the measure steward. Since the measure steward has removed its support to update this measure in 2017, CMS proposes removal of the measure.	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement

MIPS ID Number	NQF/ PQRS	CMS E-Measure ID	Data Submission Method	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
	N/A/ 425	N/A	Claims, Registry	Effective Clinical Care	Photodocumentation of Cecal Intubation The rate of screening and surveillance colonoscopies for which photodocumentation of landmarks of cecal intubation is performed to establish a complete examination **Rationale:** Due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure. This measure is related to one of the conditions covered under the Core Measure Collaborative but is not included in the core measure set. The clinical performance identified with this measure can be addressed by the measures within the core measure set.	American College of Gastroenterology/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy

TABLE G: Measures Proposed with Substantive Changes for MIPS Reporting in 2017

Measure Title:	Diabetes: Hemoglobin A1c Poor Control
MIPS ID Number:	N/A
NQF/PQRS #:	0059/001
CMS E-Measure ID:	CMS122v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data Submission Method:	Claims, Web Interface, Registry, EHR, Measures Group
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period
Proposed Substantive Change	• Revise Measure Title to read: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%) • Revise data submission method to remove Measures Group
Steward:	National Committee for Quality Assurance
Rationale:	CMS proposes a change to measure description that would clarify the definition of Hemoglobin A1c required for poor control. This change does not constitute a change in measure intent or logic coding. Hemoglobin A1c >9.0% is consistent with clinical guidelines and practice. Additionally, in response to the proposed MIPS policy that no longer includes Measures Group, this measure is being removed from Measures Group as a data submission method.
Measure Title:	Coronary Artery Disease (CAD): Antiplatelet Therapy
MIPS ID Number:	N/A
NQF/PQRS #:	0067/006
CMS E-Measure ID:	N/A
National Quality	Effective Clinical Care

Strategy Domain:	
Current Data Submission Method:	Registry, Measures Group
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period
Proposed Substantive Change	• Revise Measure Title to read: Chronic Stable Coronary Artery Disease (CAD): Antiplatelet Therapy • Revise data submission method to remove Measures Group
Steward:	National Committee for Quality Assurance
Rationale:	CMS proposes a change to measure title to align with the NQF endorsed version of this measure and to clarify the intent of the measure. This change does not constitute a change in measure intent. The measure description remains the same where patients diagnosed with CAD are prescribed an antiplatelet within 12 months. Additionally, in response to the proposed MIPS policy that no longer includes Measures Group, this measure is being removed from Measures Group as a data submission method.
Measure Title:	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
MIPS ID Number:	N/A
NQF/PQRS #:	0083/008
CMS E-Measure ID:	CMS144v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data Submission Method:	Web Interface, Registry, EHR, Measures Group
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge
Proposed Substantive Change	• Revise data submission method to remove from the Web Interface
Steward:	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
Rationale:	CMS proposes to change the reporting mechanism for this measure by removing it from the Web Interface. The Web Interface measure set contains measures for primary care and also includes relevant measures from the core measure set. This measure is not a measure in the core set and is being proposed for removal from the Web Interface to align the Web Interface measure set with the core measure set.
Measure Title:	Medication Reconciliation Post-Discharge
MIPS ID Number:	N/A
NQF/PQRS #:	0097/046
CMS E-Measure ID:	N/A

National Quality Strategy Domain:	Communication and Care Coordination
Current Data Submission Method:	Claims, Registry
Current Measure Description:	The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older
Proposed Substantive Change	• Revise data submission method to add the Web Interface
Steward:	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes to change the data submission method for this measure by adding it to the Web Interface. The Web Interface measure set contains measures for primary care and also includes relevant measures from the core measure set. This measure is a core measure and is being proposed for the Web Interface to align the Web Interface measure set with the core measure set. Furthermore, this measure is replacing PQRS #130: Documentation of Current Medications in the Medical Record in the Web Interface.
Measure Title:	Appropriate Testing for Children with Pharyngitis
MIPS ID Number:	N/A
NQF/PQRS #:	N/A (previously 0002)/066
CMS E-Measure ID:	CMS146v4
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Data submission Method:	Registry, EHR
Current Measure Description:	Percentage of children 2-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode
Proposed Substantive Change	• Revise Measures description to read: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode • Remove NQF #0002
Steward:	National Committee on Quality Assurance
Rationale:	CMS proposes the change in the measure description due to guideline changes in 2013 where the age range changed to 3-18. Furthermore, this measure is no longer endorsed by the National Quality Forum (NQF), therefore, CMS proposes to remove

	the NQF number as a reference for this measure.
Measure Title:	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
MIPS ID Number:	N/A
NQF/PQRS #:	0389/102
CMS E-Measure ID:	CMS129v5
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Data submission Method:	Registry, EHR
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer
Proposed Substantive Change	• Revise measure description to read: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer
Steward:	American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes changes to the measure description due to a change in clinical guidelines that in include very low and low risk of prostate cancer recurrence. CMS believes that this change does not change the intent of the measure but merely ensures the measure remains up-to-date according to clinical guidelines and practice.
Measure Title:	Breast Cancer Screening
MIPS ID Number:	N/A
NQF/PQRS #:	2372 (previously not applicable)/112
CMS E-Measure ID:	CMS125v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Claims, Web Interface, Registry, EHR, Measures Group
Current Measure Description:	Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer
Proposed Substantive Change	• Revise Measures description to read: Percentage of women 50-74 years of age who had a mammogram to screen for breast cancer • Add NQF # 2372 which was not previously applicable • Revise data submission method to remove Measures Group
Steward:	National Committee on Quality Assurance
Rationale:	CMS proposes a substantive change to the measure due to clinical guideline changes that occurred in 2013 which changed the age requirement for mammograms from 40-69 years to 50-74 years. CMS believes that this change does not change the intent of the measure but merely ensures the measure remains up-

	to-date according to clinical guidelines and practice. Additionally, in response to the proposed MIPS policy that no longer includes Measures Group, this measure is being removed from Measures Group as a data submission method. Furthermore, this measure has been recently endorsed by NQF with the updated age range. Therefore, CMS proposes to add the NQF #2372 to the measure.
Measure Title:	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)
MIPS ID Number:	N/A
NQF/PQRS #:	0066/118
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Web Interface, Registry
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy
Proposed Substantive Change	• Revise data submission method to remove from the Web Interface
Steward:	American College of Cardiology/ American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes to change the data submission method for this measure by removing it from the Web Interface. The Web Interface measure set contains measures for primary care and also includes relevant measures from the core measure set. This measure is not a measure in the core set and is being proposed for removal from the Web Interface to align the Web Interface measure set with the core measure set.
Measure Title:	Diabetes: Urine Protein Screening
MIPS ID Number:	N/A
NQF/PQRS #:	0062/119
CMS E-Measure ID:	CMS134v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Registry, EHR, Measures Group
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period
Proposed Substantive Change	• Revise measure title to read: Diabetes: Medical Attention for Nephropathy • Revise data submission method to remove Measures Group
Steward:	National Committee for Quality Assurance

Rationale:	CMS proposes the title of this measure change to align with the measure's intent to increase reporting clarity and to match the NQF endorsed measure's title. Additionally, in response to the proposed MIPS policy that no longer includes Measures Group, this measure is being removed from Measures Group as a data submission method.
Measure Title:	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
MIPS ID Number:	N/A
NQF/PQRS #:	0421/128
CMS E-Measure ID:	CMS69v4
National Quality Strategy Domain:	Community/Population Health
Current Data submission Method:	Claims, Web Interface, Registry, Measures Group
Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter Normal Parameters: -Age 65 years and older BMI => 23 and < 30 kg/m2 -Age 18 - 64 years BMI => 18.5 and < 25 kg/m2
Proposed Substantive Change	• Remove upper parameter from measure description. Revise description to read: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter Normal Parameters: Age 18 - 64 years BMI => 18.5 and < 25 kg/m2 • Revise data submission method to remove Measures Group
Steward:	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
Rationale:	CMS proposes to remove the upper parameter from the measure description to align with the recommendations of technical expert panel and clinical expertise. Additionally, in response to the proposed MIPS policy that no longer includes Measures Group, this measure is being removed from Measures Group as a data submission method.
Measure Title:	Documentation of Current Medications in the Medical Record
MIPS ID Number:	N/A
NQF/PQRS #:	0419/130
CMS E-Measure ID:	CMS68v5
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Claims, Web Interface, Registry, EHR, Measures Group

Measure Description:	Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration
Proposed Substantive Change	• Revise data submission method to remove from the Web Interface and Measures Group. Measure will remain reportable via Claims, EHR, and Registry
Steward:	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
Rationale:	CMS proposes to revise the data submission method of this measure to remove it from use in the Web Interface. This measure is being replaced in the Web Interface with the core measure, PQRS #46: Medication Reconciliation Post-Discharge. Since these measures cover similar topic areas, CMS proposes to remove this measure from the Web Interface. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being removed from Measures Group.
Measure Title:	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan
MIPS ID Number:	N/A
NQF/PQRS #:	0418/134
CMS E-Measure ID:	CMS2v5
National Quality Strategy Domain:	Community/Population Health
Current Data submission Method:	Claims, Web Interface, Registry, EHR, Measures Group
Measure Description:	Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen
Proposed Substantive Change	• Revise measure title to read: Preventive Care and Screening: Screening for Depression and Follow-Up Plan • Revise measure description to read: Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen • Revise data submission method to remove from Measures Group
Steward:	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
Rationale:	CMS proposes the substantive change to revise the title and measure description to align with the recommendations of technical expert panel and clinical expertise in the field. CMS believes the revision provides clarity to providers when reporting. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being removed from Measures Group.

Measure Title:	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
MIPS ID Number:	N/A
NQF/PQRS #:	0405/160
CMS E-Measure ID:	52v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	EHR, Measures Group
Measure Description:	Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis
Proposed Substantive Change	• Change data submission method to remove Measures Group and have this measure be reportable as EHR only
Steward:	National Committee for Quality Assurance
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group to EHR only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being removed from Measures Group.
Measure Title:	Diabetes: Foot Exam
MIPS ID Number:	N/A
NQF/PQRS #:	0056/163
CMS E-Measure ID:	CMS123v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	EHR
Current Measure Description:	Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period
Proposed Substantive Change	• Revise measure description to read: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year
Steward:	National Committee for Quality Assurance
Rationale:	CMS proposes to revise the measure description to improve clarity for providers about what constitutes a foot exam. CMS believes this change does not change the intent of the measure, but merely provides clarity in response to provider feedback.
Measure Title:	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate
MIPS ID Number:	N/A
NQF/PQRS #:	0130/165
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission	Measures Group

Method:	
Measure Description:	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	Society of Thoracic Surgeons
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Coronary Artery Bypass Graft (CABG): Stroke
MIPS ID Number:	N/A
NQF/PQRS #:	0131/166
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	Society of Thoracic Surgeons
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure
MIPS ID Number:	N/A
NQF/PQRS #:	0114/167
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission	Measures Group

Method:	
Measure Description:	Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	Society of Thoracic Surgeons
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration
MIPS ID Number:	N/A
NQF/PQRS #:	0115/168
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	Society of Thoracic Surgeons
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Rheumatoid Arthritis (RA): Tuberculosis Screening
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/176
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission	Measures Group

Method:	
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)
Proposed Substantive Change	- Change data submission method from Measures Group only to Registry
Steward:	American College of Rheumatology
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/177
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months
Proposed Substantive Change	- Change data submission method from Measures Group only to Registry reporting
Steward:	American College of Rheumatology
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/179
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission	Measures Group

Method:	
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Rheumatology
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Rheumatoid Arthritis (RA): Glucocorticoid Management
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/180
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Rheumatology
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Stroke and Stroke Rehabilitation: Thrombolytic Therapy
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/187
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data	Registry

submission Method:	
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well
Proposed Substantive Change	• Change measure type from outcome measure to process measure
Steward:	American Society of Anesthesiologists/ The Joint Commission
Rationale:	CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure.
Measure Title:	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic
MIPS ID Number:	N/A
NQF/PQRS #:	0068/204
CMS E-Measure ID:	CMS164v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Claims, Web Interface, Registry, EHR, Measures Group
Current Measure Description:	Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antithrombotic during the measurement period
Proposed Substantive Change	• Revise measure title to read: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet • Revise measure description to read: Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period • Revise data submission method to remove from Measures Group
Steward:	National Committee for Quality Assurance
Rationale:	CMS proposes to revise the measure title and description to align with the measure's intent and to provide clarity for providers. Additionally, in response to the proposed MIPS policy to no longer include measure groups as a data submission method, this measure is being removed from measure group.
Measure Title:	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0422/217

CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Registry
Current Measure Type:	Process
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with Knee Impairments • Revise measure description to read: A self-report measure of change in functional status for patients 18 year+ with knee impairments. The change in functional status assessed using FOTO's (knee) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality • Revise measure type from a process measure to an outcome measure
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the change in functional status score and denominator details that include patients that completed the FOTO knee FS PROM at admission and discharge. Additionally, this change in numerator and denominator details entails that the measure type changes from process to outcome
Measure Title:	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0423/218
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Registry
Current Measure Type:	Outcome
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with Hip Impairments • Revise measure description to read: A self-report measure of change in functional status for patients 18 years+ with hip impairments. The change in

	functional status assessed using FOTO's (hip) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the average change in functional status scores in patients who were treated in a 12 month period and denominator details that include patients that completed the FOTO hip FS PROM at admission and discharge.
Measure Title:	Functional Deficit: Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0424/219
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Registry
Current Measure Type:	Outcome
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with Foot and Ankle Impairments • Revise measure description to read: A self-report measure of change in functional status for patients 18 years+ with foot and ankle impairments. The change in functional status assessed using FOTO's (foot and ankle) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the average change in functional status score in patients who were treated in a 12-month period and denominator details that include patients that completed the FOTO foot and ankle PROM at admission and discharge.
Measure Title:	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0425/220
CMS E-Measure ID:	N/A

National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Registry
Current Measure Type:	Outcome
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with Lumbar Impairments • Revise measure description to read: A self-report outcome measure of functional status for patients 18 years+ with lumbar impairments. The change in functional status assessed using FOTO's (lumbar) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the average functional status score for patients treated in a 12-month period compared to a standard threshold and denominator details that include patients that completed the FOTO (lumbar) PROM.
Measure Title:	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0426/221
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Registry
Current Measure Type:	Outcome
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with Shoulder Impairments • Revise measure description to read: A self-report outcome measure of change in functional status for patients 18 years+ with shoulder impairments. The change in functional status assessed using FOTO's (shoulder) PROM is adjusted to patient characteristics known to be

	associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the average functional status score in patients treated in a 12-month period and denominator details that include patients that completed the FOTO shoulder FS outcome instrument at admission and discharge.
Measure Title:	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0427/222
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Registry
Current Measure Type:	Outcome
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the elbow, wrist or hand in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with Elbow, Wrist and Hand Impairments • Revise measure description to read: A self-report outcome measure of functional status for patients 18 years+ with elbow, wrist and hand impairments. The change in functional status assessed using FOTO's (elbow, wrist and hand) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the average functional status scores for patients treated over a 12 month period and denominator details that include patients that completed the FOTO (elbow, wrist, and hand) PROM.
Measure Title:	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments
MIPS ID Number:	N/A
NQF/PQRS #:	0428/223
CMS E-Measure ID:	N/A
National Quality	Communication and Care Coordination

Strategy Domain:	
Current Data submission Method:	Registry
Current Measure Type:	Outcome
Current Measure Description:	Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the neck, cranium, mandible, thoracic spine, ribs, or other general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured
Proposed Substantive Change	• Revise measure title to read: Functional Status Change for Patients with General Orthopedic Impairments • Revise measure description to read: A self-report outcome measure of functional status for patients 18 years+ with general orthopedic impairments. The change in functional status assessed using FOTO (general orthopedic) PROM is adjusted to patient characteristics known to be associated with functional status outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Steward:	Focus on Therapeutic Outcomes, Inc.
Rationale:	CMS proposes to revise the measure title and description to align with the NQF-endorsed version of the measure. The measure owner revised the title and description of the measure to be consistent with the change in numerator details that now calculate the change in functional status scores for patients over a 12 month period and denominator details that include patients that completed the FOTO (general orthopedic) PROM.
Measure Title:	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy
MIPS ID Number:	N/A
NQF/PQRS #:	1814/268
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Claims, Registry
Current Measure Description:	All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year
Proposed Substantive Change	• Change measure type from outcome measure to process measure
Steward:	American Academy of Neurology
Rationale:	CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis of the measure specification, CMS proposes to revise the classification of this measure to process measure. This would be consistent with the clinical action required for the measure and would

	align the measure type with the NQF-endorsed version.
Measure Title:	Sleep Apnea: Assessment of Sleep Symptoms
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/276
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Sleep Apnea: Assessment of Sleep Symptoms
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/277
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measure Group as a data submission method, this measure is being proposed as an

	individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Sleep Apnea: Positive Airway Pressure Therapy Prescribed
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/278
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/279
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition.

	Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Dementia: Functional Status Assessment
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/282
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Neurology/ American Psychiatric Association
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Dementia: Neuropsychiatric Symptom Assessment
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/283
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Neurology/ American Psychiatric Association
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include

	Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Dementia: Management of Neuropsychiatric Symptoms
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/284
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Neurology/ American Psychiatric Association
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Dementia: Counseling Regarding Safety Concerns
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/286
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Neurology/ American Psychiatric Association
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as

	an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Dementia: Caregiver Education and Support
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/288
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American Academy of Neurology/ American Psychiatric Association
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/290
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Academy of Neurology
Rationale:	CMS proposes to change the data submission for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes

	this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis of the measure specification, CMS proposes to revise the classification of this measure to process measure to match the clinical action of psychiatric disease assessment.
Measure Title:	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/291
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Academy of Neurology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure in order to match the clinical action of assessment of cognitive impairment.
Measure Title:	Parkinson's Disease: Rehabilitative Therapy Options
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/293
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually
Proposed	• Change data submission method from Measures Group only to Registry

Substantive Change	• Change measure type from outcome measure to process measure
Steward:	American Academy of Neurology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure in order to match the clinical action of communication about therapy options.
Measure Title:	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/294
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Academy of Neurology
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure in order to match the clinical action of communicating treatment options.
Measure Title:	Cervical Cancer Screening
MIPS ID Number:	N/A
NQF/PQRS #:	0032/309

CMS E-Measure ID:	CMS124v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	EHR
Current Measure Description:	Percentage of women 21-64 years of age, who received one or more Pap tests to screen for cervical cancer
Proposed Substantive Change	• Revise Measure description to read: Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: - Women age 21–64 who had cervical cytology performed every 3 years - Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years
Steward:	National Committee on Quality Assurance
Rationale:	CMS proposes to change the measure description of this measure to align with measure intent and 2012 USPSTF recommendation: U.S. Preventive Services Task Force. 2012. "Screening for Cervical Cancer: U.S. Preventive Services Task Force Recommendation Statement." Ann Intern Med. 156(12):880-91.
Measure Title:	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/317
CMS E-Measure ID:	CMS22v4
National Quality Strategy Domain:	Community/Population Health
Current Data submission Method:	Claims, Web Interface, Registry, EHR, Measures Group
Current Measure Description:	Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Proposed Substantive Change	• Revise data submission method to remove from Web Interface and Measures Group
Steward:	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
Rationale:	CMS proposes a change to the data submission method for this measure and remove it from the Web Interface. The Web Interface measure set contains measures for primary care and also includes relevant measures from the core measure set. This measure is not a core measure and is being removed to align the Web Interface measure set with the core measure set. Additionally, in response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being removed from Measures Group.
Measure Title:	Pediatric Kidney Disease: Adequacy of Volume Management
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/327

CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Registry
Measure Description:	Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.
Proposed Substantive Change	• Change measure type from outcome measure to process measure
Steward:	Renal Physicians Association
Rationale:	CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS understands this measure to be a percentage of documented assessment rather than a health outcome. Therefore, CMS proposes to revise the classification of this measure to process.
Measure Title:	HIV Viral Load Suppression
MIPS ID Number:	N/A
NQF/PQRS #:	2082/338
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	Health Resources and Services Administration
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	HIV Medical Visit Frequency

MIPS ID Number:	N/A
NQF/PQRS #:	2079/340
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	Health Resources and Services Administration
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/350
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. Nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Association of Hip and Knee Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this

	measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure in order to match the clinical action of shared decision-making.
Measure Title:	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/351
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke)
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Association of Hip and Knee Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure.
Measure Title:	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/352
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients regardless of age or gender undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet

Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Association of Hip and Knee Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure.
Measure Title:	Total Knee Replacement: Identification of Implanted
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/353
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients regardless of age or gender undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry • Change measure type from outcome measure to process measure
Steward:	American Association of Hip and Knee Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measure Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure. Additionally, CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to process measure.
Measure Title:	Anastomotic Leak Intervention
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/354
CMS E-Measure ID:	N/A

National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Unplanned Reoperation within the 30 Day Postoperative Period
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/355
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period
Proposed Substantive Change	• Change data submission measure from Measures Group only to Registry
Steward:	American College of Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Unplanned Hospital Readmission within 30 Days of Principal Procedure
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/356
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data	Measures Group

submission Method:	
Measure Description:	Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Surgical Site Infection (SSI)
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/357
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Measures Group
Measure Description:	Percentage of patients aged 18 years and older who had a surgical site infection (SSI)
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Surgeons
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/359
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group

Measure Description:	Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems
Proposed Substantive Change	- Change data submission method from Measures Group only to Registry
Steward:	American College of Radiology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/360
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study
Proposed Substantive Change	- Change data submission method from Measures Group only to Registry
Steward:	American College of Radiology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/361
CMS E-Measure ID:	N/A

National Quality Strategy Domain:	Patient Safety
Current Data submission Method:	Measures Group
Measure Description:	Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Radiology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/362
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Radiology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.

Measure Title:	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/363
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry
Steward:	American College of Radiology
Rationale:	CMS proposes to change the data submission method for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/364
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Data submission Method:	Measures Group
Measure Description:	Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors
Proposed Substantive Change	• Change data submission method from Measures Group only to Registry

Steward:	American College of Radiology
Rationale:	CMS proposes to change the reporting mechanism for this measure from Measures Group only to Registry only. As part of a measures group, this measure was part of a metric that provided relevant content for a specific condition. In response to the proposed MIPS policy to no longer include Measures Group as a data submission method, this measure is being proposed as an individual measure. CMS believes this measure continues to address a clinical performance gap even if it is reported as an individual measure.
Measure Title:	Depression Remission at Twelve Months
MIPS ID Number:	N/A
NQF/PQRS #:	0710/370
CMS E-Measure ID:	CMS159v4
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Web interface, Registry, EHR
Measure Description:	Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment
Proposed Substantive Change	• Revise measure description to read: Patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire (PHQ-9) score greater than nine who demonstrate remission at twelve months (+/- 30 days) after an index visit) defined as a PHQ-9 score less than five. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment. • Change measure type from intermediate outcome measure to outcome measure
Steward:	Minnesota Community Measurement
Rationale:	CMS proposes to revise the measure description to provide clarity for reporting. This does not change the intent of the measure but merely provides clarity to ensure consistent reporting for eligible clinicians. Additionally, CMS proposes to change this measure type designation from intermediate outcome measure to outcome measure. This measure was previously finalized in PQRS as an intermediate outcome measure. However, upon further review and analysis, CMS proposes to revise the classification of this measure to outcome measure in order to match the outcome of depression remission.
Measure Title:	Functional Status Assessment for Knee Replacement
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/375
CMS E-Measure ID:	CMS66v4
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Data submission	EHR

Method:	
Measure Description:	Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments.
Proposed Substantive Change	• Revise measure title to read: Functional Status Assessment for Total Knee Replacement • Revise measure description to read: Percentage of patients 18 years of age and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported functional status assessments
Steward:	Centers for Medicare & Medicaid Services/ National Committee for Quality Assurance
Rationale:	CMS proposes to revise the title and description of the measure to align with the intent of the measure. This does not change the intent of the measure but merely provides clarity to ensure consistent reporting for eligible clinicians.
Measure Title:	Functional Status Assessment for Hip Replacement
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/376
CMS E-Measure ID:	CMS56v4
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Data submission Method:	EHR
Measure Description:	Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments
Proposed Substantive Change	• Revise title to read: Functional Status Assessment for Total Hip Replacement • Revise measure description to read: Percentage of patients 18 years of age and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments
Steward:	Centers for Medicare & Medicaid Services/ National Committee for Quality Assurance
Rationale:	CMS proposes to revise the title and description of the measure to align with the intent of the measure. This change addresses concerns does not change the intent of the measure but merely provides clarity to ensure consistent reporting for eligible clinicians.
Measure Title:	Functional Status Assessment for Complex Chronic Conditions
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/377
CMS E-Measure ID:	CMS90v5
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Data submission Method:	EHR
Measure	Percentage of patients aged 65 years and older with heart failure who completed

Description:	initial and follow-up patient-reported functional status assessments
Proposed Substantive Change	• Revise measure title to read: Functional Status Assessments for Patients with Congestive Heart Failure • Revise measure description to read: Percentage of patients 65 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments
Steward:	Centers for Medicare & Medicaid Services/ Mathematica
Rationale:	CMS proposes to revise the title and description of the measure to add clarity in response to provider feedback. This does not change the intent of the measure but merely provides clarity to ensure consistent reporting for eligible clinicians.
Measure Title:	Varicose Vein Treatment with Saphenous Ablation: Outcome Survey
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/420
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Registry
Current Measure Description:	Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.
Proposed Substantive Change	• Change measure type from process measure to outcome measure
Steward:	Society of Interventional Radiology
Rationale:	CMS proposes to change this measure type designation from process measure to outcome measure. This measure was previously finalized in PQRS as a process measure. However, upon further review and analysis of the measure specification, CMS proposes to revise the classification of this measure to outcome measure because it assesses improvement on a patient reported outcome survey instrument.
Measure Title:	Appropriate Assessment of Retrievable Inferior Vena Cava Filters for Removal
MIPS ID Number:	N/A
NQF/PQRS #:	N/A/421
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data submission Method:	Registry
Current Measure Description:	Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at

	least two attempts
Proposed Substantive Change	- Change measure type from outcome measure to process measure
Steward:	Society of Interventional Radiology
Rationale:	CMS proposes to change this measure type designation from outcome measure to process measure. This measure was previously finalized in PQRS as an outcome measure. However, upon further review and analysis of the measure specification, CMS proposes to revise the classification of this measure to process measure in order to match the clinical action of appropriate care assessment.

Table H: Proposed Clinical Practice Improvement Activities Inventory

We invite comment on the reassignment of CPIA activities under alternate subcategories, and on the scoring weights assigned to CPIA activities.

Subcategory	**Activity**	**Weighting**
Expanded Practice Access	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.	High
Expanded Practice Access	Use of telehealth services and analysis of data for quality improvement, such as participation in remote specialty care consults, or teleaudiology pilots that assess ability to still deliver quality care to patients.	Medium
Expanded Practice Access	Collection of patient experience and satisfaction data on access to care and development of an improvement plan, such as outlining steps for improving communications with patients to help understanding of urgent access needs.	Medium
Expanded Practice Access	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services (e.g., investment of on-site diabetes educator).	Medium
Population Management	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, patient self-management program)for 60 percent of practice patients in year 1 and 75 percent of practice patients in year 2 who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).	High

Subcategory	Activity	Weighting
Population Management	MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, in the first performance year, 60 percent or more of their ambulatory care patients receiving warfarin are being managed by one or more of these clinical practice improvement activities: Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care*, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; and/or For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program. The performance threshold will increase to 75 percent for the second performance year and onward. Clinicians would attest that, 60 percent for first year, or 75 percent for the second year, of their ambulatory care patients receiving warfarin participated in an anticoagulation management program for at least 90 days during the performance period.	High

Subcategory	Activity	Weighting
Population Management	Participating in a Rural Health Clinic (RHC), Indian Health Service (IHS), or Federally Qualified Health Center in ongoing engagement activities that contribute to more formal quality reporting, and that include receiving quality data back for broader quality improvement and benchmarking improvement which will ultimately benefit patients. Participation in Indian Health Service, as a CPIA, requires MIPS eligible clinicians and groups to deliver care to federally recognized American Indian and Alaska Native populations in the U.S. and in the course of that care implement continuous clinical practice improvement including reporting data on quality of services being provided and receiving feedback to make improvements over time.	Medium
Population Management	For outpatient Medicare beneficiaries with diabetes and who are prescribed antidiabetic agents (e.g., insulin, sulfonylureas), MIPS eligible clinicians and groups must attest to having: For the first performance year, at least 60 percent of medical records with documentation of an individualized glycemic treatment goal that: a) Takes into account patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and b) Is reassessed at least annually. The performance threshold will increase to 75 percent for the second performance year and onward. Clinicians would attest that, 60 percent for first year, or 75 percent for the second year, of their medical records that document individualized glycemic treatment represent patients who are being treated for at least 90 days during the performance period.	High
Population Management	Take steps to improve health status of communities, such as collaborating with key partners and stakeholders to implement evidenced-based practices to improve a specific chronic condition. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist MIPS eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.	Medium

Subcategory	**Activity**	**Weighting**
Population Management	Take steps to improve healthcare disparities, such as Population Health Toolkit or other resources identified by CMS, the Learning and Action Network, Quality Innovation Network, or National Coordinating Center. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.	Medium
Population Management	Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.	High
Population Management	Participation in CMMI models such as Million Hearts Campaign.	Medium
Population Management	Participation in research that identifies interventions, tools or processes that can improve a targeted patient population.	Medium
Population Management	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (e.g., comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).	Medium
Population Management	Implementation of regular reviews of targeted patient population needs which includes access to reports that show unique characteristics of eligible professional's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.	Medium

Subcategory	Activity	Weighting
Population Management	Empanel (assign responsibility for) the total population, linking each patient to a MIPS eligible clinician or group or care team. Empanelment is a series of processes that assign each active patient to a MIPS eligible clinician or group and/or care team, confirm assignment with patients and clinicians, and use the resultant patient panels as a foundation for individual patient and population health management. Empanelment identifies the patients and population for whom the MIPS eligible clinician or group and/or care team is responsible and is the foundation for the relationship continuity between patient and MIPS eligible clinician or group /care team that is at the heart of comprehensive primary care. Effective empanelment requires identification of the "active population" of the practice: those patients who identify and use your practice as a source for primary care. There are many ways to define "active patients" operationally, but generally, the definition of "active patients" includes patients who have sought care within the last 24 to 36 months, allowing inclusion of younger patients who have minimal acute or preventive health care.	Medium

Subcategory	Activity	Weighting
Population Management	Proactively manage chronic and preventive care for empaneled patients that could include one or more of the following: Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; plan of care for chronic conditions; and advance care planning; Use condition-specific pathways for care of chronic conditions (e.g., hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target; Use pre-visit planning to optimize preventive care and team management of patients with chronic conditions; Use panel support tools (registry functionality) to identify services due; Use reminders and outreach (e.g., phone calls, emails, postcards, patient portals and community health workers where available) to alert and educate patients about services due; and/or Routine medication reconciliation.	Medium
Population Management	Provide longitudinal care management to patients at high risk for adverse health outcome or harm that could include one or more of the following: Use a consistent method to assign and adjust global risk status for all empaneled patients to allow risk stratification into actionable risk cohorts. Monitor the risk-stratification method and refine as necessary to improve accuracy of risk status identification; Use a personalized plan of care for patients at high risk for adverse health outcome or harm, integrating patient goals, values and priorities; and/or Use on-site practice-based or shared care managers to proactively monitor and coordinate care for the highest risk cohort of patients.	Medium

Subcategory	Activity	Weighting
Population Management	Provide episodic care management, including management across transitions and referrals that could include one or more of the following: Routine and timely follow-up to hospitalizations, ED visits and stays in other institutional settings, including symptom and disease management, and medication reconciliation and management; and/or Managing care intensively through new diagnoses, injuries and exacerbations of illness.	Medium
Population Management	Manage medications to maximize efficiency, effectiveness and safety that could include one or more of the following: Reconcile and coordinate medications and provide medication management across transitions of care settings and eligible clinicians or groups; Integrate a pharmacist into the care team; and/or Conduct periodic, structured medication reviews.	Medium
Care Coordination	Performance of regular practices that include providing specialist reports back to the referring MIPS eligible clinician or group to close the referral loop or where the referring MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the certified EHR technology.	Medium
Care Coordination	Timely communication of test results defined as timely identification of abnormal test results with timely follow-up.	Medium
Care Coordination	Implementation of at least one additional recommended activity from the Quality Innovation Network-Quality Improvement Organization after technical assistance has been provided related to improving care coordination.	Medium
Care Coordination	Participation in the CMS Transforming Clinical Practice Initiative.	High
Care Coordination	Membership and participation in a CMS Partnership for Patients Hospital Engagement Network.	Medium

Subcategory	**Activity**	**Weighting**
Care Coordination	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (e.g., documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).	Medium
Care Coordination	Implementation of regular care coordination training.	Medium
Care Coordination	Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved and communications from date patient is scheduled for outpatient procedure through day of procedure).	Medium
Care Coordination	Implementation of practices/processes to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s).	Medium
Care Coordination	Implementation of practices/processes for care transition that include documentation of how a MIPS eligible clinician or group carried out a patient-centered action plan for first 30 days following a discharge (e.g., staff involved, phone calls conducted in support of transition, accompaniments, navigation actions, home visits, patient information access, etc.).	Medium
Care Coordination	Establish standard operations to manage transitions of care that could include one or more of the following: Establish formalized lines of communication with local settings in which empaneled patients receive care to ensure documented flow of information and seamless transitions in care; and/or Partner with community or hospital-based transitional care services.	Medium

Subcategory	Activity	Weighting
Care Coordination	Establish effective care coordination and active referral management that could include one or more of the following: Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements; Track patients referred to specialist through the entire process; and/or Systematically integrate information from referrals into the plan of care.	Medium
Care Coordination	Ensure that there is bilateral exchange of necessary patient information to guide patient care that could include one or more of the following: Participate in a Health Information Exchange if available; and/or Use structured referral notes.	Medium
Care Coordination	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; and/or Provide a guide to available community resources.	Medium
Beneficiary Engagement	In support of improving patient access, performing additional activities that enable capture of patient reported outcomes (e.g., home blood pressure, blood glucose logs, food diaries, at-risk health factors such as tobacco or alcohol use, etc.) or patient activation measures through use of certified EHR technology, containing this data in a separate queue for clinician recognition and review.	Medium

Subcategory	Activity	Weighting
Beneficiary Engagement	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.	Medium
Beneficiary Engagement	Engagement with a Quality Innovation Network-Quality Improvement Organization, which may include participation in self-management training programs such as diabetes.	Medium
Beneficiary Engagement	Access to an enhanced patient portal that provides up to date information related to relevant chronic disease health or blood pressure control, and includes interactive features allowing patients to enter health information and/or enables bidirectional communication about medication changes and adherence.	Medium
Beneficiary Engagement	Enhancements and ongoing regular updates and use of websites/tools that include consideration for compliance with section 508 of the Rehabilitation Act of 1973 or for improved design for patients with cognitive disabilities. Refer to the CMS website on Section 508 of the Rehabilitation Act https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/index.html?redirect=/InfoTechGenInfo/07_Section508.asp that requires that institutions receiving federal funds solicit, procure, maintain and use all electronic and information technology (EIT) so that equal or alternate/comparable access is given to members of the public with and without disabilities. For example, this includes designing a patient portal or website that is compliant with section 508 of the Rehabilitation Act of 1973.	Medium
Beneficiary Engagement	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.	High
Beneficiary Engagement	Participation in a QCDR, that promotes use of patient engagement tools.	Medium
Beneficiary Engagement	Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.	Medium
Beneficiary Engagement	Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.	Medium
Beneficiary Engagement	Participation in a QCDR, that promotes implementation of patient self-action plans.	Medium
Beneficiary Engagement	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.	Medium

Subcategory	Activity	Weighting
Beneficiary Engagement	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.	Medium
Beneficiary Engagement	Use evidence-based decision aids to support shared decision-making.	Medium
Beneficiary Engagement	Regularly assess the patient experience of care through surveys, advisory councils, and/or other mechanisms.	Medium
Beneficiary Engagement	Engage patients and families to guide improvement in the system of care.	Medium
Beneficiary Engagement	Engage patients, family and caregivers in developing a plan of care and prioritizing their goals for action, documented in the certified EHR technology.	Medium
Beneficiary Engagement	Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, teach back, action planning or motivational interviewing.	Medium
Beneficiary Engagement	Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).	Medium
Beneficiary Engagement	Provide peer-led support for self-management.	Medium
Beneficiary Engagement	Use group visits for common chronic conditions (e.g., diabetes).	Medium
Beneficiary Engagement	Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community.	Medium
Beneficiary Engagement	Provide self-management materials at an appropriate literacy level and in an appropriate language.	Medium
Beneficiary Engagement	Provide a pre-visit development of a shared visit agenda with the patient.	Medium
Beneficiary Engagement	Provide coaching between visits with follow-up on care plan and goals.	Medium
Patient Safety and Practice Assessment	Participation in an AHRQ-listed patient safety organization.	Medium

Subcategory	**Activity**	**Weighting**
Patient Safety and Practice Assessment	Participation in Maintenance of Certification Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.	Medium
Patient Safety and Practice Assessment	For eligible professionals not participating in Maintenance of Certification (MOC) Part IV, new engagement for MOC Part IV, such as IHI Training/Forum Event; National Academy of Medicine, AHRQ Team STEPPS®.	Medium
Patient Safety and Practice Assessment	Administration of the AHRQ Survey of Patient Safety Culture and submission of data to the comparative database (refer to AHRQ Survey of Patient Safety Culture website **http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html**)	Medium
Patient Safety and Practice Assessment	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.	Medium
Patient Safety and Practice Assessment	Consultation of **Prescription Drug Monitoring Program** prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription that lasts for longer than 3 days.	High
Patient Safety and Practice Assessment	Use of QCDR data, for ongoing practice assessment and improvements in patient safety.	Medium
Patient Safety and Practice Assessment	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of the Surgical Risk Calculator.	Medium
Patient Safety and Practice Assessment	Completion of the American Medical Association's STEPS Forward program.	Medium
Patient Safety and Practice Assessment	Completion of training and obtaining an approved waiver for provision of medication -assisted treatment of opioid use disorders using buprenorphine.	Medium

Subcategory	**Activity**	**Weighting**
Patient Safety and Practice Assessment	Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).	Medium
Patient Safety and Practice Assessment	Participation in designated private payer clinical practice improvement activities.	Medium
Patient Safety and Practice Assessment	Participation in Joint Commission Ongoing Professional Practice Evaluation initiative.	Medium
Patient Safety and Practice Assessment	Participation in other quality improvement programs such as Bridges to Excellence.	Medium
Patient Safety and Practice Assessment	Implementation of an antibiotic stewardship program that measures the appropriate use of antibiotics for several different conditions (URI Rx in children, diagnosis of pharyngitis, Bronchitis Rx in adults) according to clinical guidelines for diagnostics and therapeutics.	Medium
Patient Safety and Practice Assessment	Use decision support and protocols to manage workflow in the team to meet patient needs.	Medium
Patient Safety and Practice Assessment	Build the analytic capability required to manage total cost of care for the practice population that could include one or more of the following: Train appropriate staff on interpretation of cost and utilization information; and/or Use available data regularly to analyze opportunities to reduce cost through improved care.	Medium
Patient Safety and Practice Assessment	Measure and improve quality at the practice and panel level that could include one or more of the following: Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group(panel); and/or Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.	Medium

Subcategory	Activity	Weighting
Patient Safety and Practice Assessment	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following: Train all staff in quality improvement methods; Integrate practice change/quality improvement into staff duties; Engage all staff in identifying and testing practices changes; Designate regular team meetings to review data and plan improvement cycles; Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families.	Medium
Patient Safety and Practice Assessment	Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following: Make responsibility for guidance of practice change a component of clinical and administrative leadership roles; Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.	Medium
Patient Safety and Practice Assessment	Implementation of fall screening and assessment programs to identify patients at risk for falls and address modifiable risk factors (e.g., clinical decision support/prompts in the electronic health record that help manage the use of medications, such as benzodiazepines, that increase fall risk).	Medium
Achieving Health Equity	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare.	High

Subcategory	Activity	Weighting
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.	Medium
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for promoting use of patient-reported outcome (PRO) tools and corresponding collection of PRO data (e.g., use of PQH-2 or PHQ-9 and PROMIS instruments).	Medium
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (e.g., use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment).	Medium
Achieving Health Equity	Participation in State Innovation Model funded activities.	Medium
Emergency Response and Preparedness	Participation in Disaster Medical Assistance Teams, or Community Emergency Responder Teams. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and MIPS eligible clinician groups must be registered for a minimum of 6 months as a volunteer for disaster or emergency response.	Medium
Emergency Response and Preparedness	Participation in domestic or international humanitarian volunteer work. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must be registered for a minimum of 6 months as a volunteer for domestic or international humanitarian volunteer work.	Medium
Integrated Behavioral and Mental Health	Diabetes screening for people with schizophrenia or bipolar disease who are using antipsychotic medication.	Medium
Integrated Behavioral and Mental Health	Tobacco use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including tobacco use screening and cessation interventions (refer to NQF #0028) for patients with co-occurring conditions of behavioral or mental health and at risk factors for tobacco dependence.	Medium

Subcategory	Activity	Weighting
Integrated Behavioral and Mental Health	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health conditions.	Medium
Integrated Behavioral and Mental Health	Depression screening and follow-up plan: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including depression screening and follow-up plan (refer to NQF #0418) for patients with co-occurring conditions of behavioral or mental health conditions.	Medium
Integrated Behavioral and Mental Health	Major depressive disorder: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including suicide risk assessment (refer to NQF #0104) for mental health patients with co-occurring conditions of behavioral or mental health conditions.	Medium
Integrated Behavioral and Mental Health	Integration facilitation, and promotion of the colocation of mental health services in primary and/or non-primary clinical care settings.	High
Integrated Behavioral and Mental Health	Offer integrated behavioral health services to support patients with behavioral health needs, dementia, and poorly controlled chronic conditions that could include one or more of the following: Use evidence-based treatment protocols and treatment to goal where appropriate; Use evidence-based screening and case finding strategies to identify individuals at risk and in need of services; Ensure regular communication and coordinated workflows between eligible clinicians in primary care and behavioral health; Conduct regular case reviews for at-risk or unstable patients and those who are not responding to treatment; Use of a registry or certified health information technology functionality to support active care management and outreach to patients in treatment; and/or Integrate behavioral health and medical care plans and facilitate integration through co-location of services when feasible.	High

Subcategory	Activity	Weighting
Integrated Behavioral and Mental Health	Enhancements to an electronic health record to capture additional data on behavioral health (BH) populations and use that data for additional decision-making purposes (e.g., capture of additional BH data results in additional depression screening for at-risk patient not previously identified).	Medium

[FR Doc. 2016–10032 Filed 4–27–16; 4:15 pm]
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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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FEDERAL REGISTER

Vol. 81 Monday,
No. 89 May 9, 2016

Part III

Department of Energy

10 CFR Parts 429, 430, and 431
Energy Conservation Program for Certain Commercial and Industrial Equipment: Test Procedure for Commercial Water Heating Equipment; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429, 430, and 431

[Docket No. EERE–2014–BT–TP–0008]

RIN 1904–AD18

Energy Conservation Program for Certain Commercial and Industrial Equipment: Test Procedure for Commercial Water Heating Equipment

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking (NOPR) and announcement of public meeting.

SUMMARY: The U.S. Department of Energy (DOE) proposes to revise its test procedures for commercial water heaters, unfired hot water storage tanks, and hot water supply boilers (henceforth, "commercial water heating (CWH) equipment") established under the Energy Policy and Conservation Act of 1975 (EPCA), as amended. In this NOPR, DOE proposes several changes, including: Updating references of industry test standards to incorporate by reference the most recent versions of the industry standards; proposing modifications to the existing test methods for certain classes of CWH equipment; developing new test procedures for determining the efficiency of unfired hot water storage tanks, commercial heat pump water heaters, and flow-activated instantaneous water heaters; proposing clarifications on test set-up and settings for various classes of CWH equipment; revising the certification requirements for CWH equipment; and proposing associated implementing regulations including definitions. DOE announces a public meeting to receive comment on these proposed test procedure amendments, and it also welcomes written comments and data from the public on all aspects of this proposal.

DATES:

Meeting: DOE will hold a public meeting on June 6, 2016, from 9:30 a.m. to 12:00 p.m., in Washington, DC. The meeting will also be broadcast as a webinar. See section V, "Public Participation," for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

Comments: DOE will accept comments, data, and information regarding this NOPR before and after the public meeting, but no later than July 8, 2016. See section V, "Public Participation," for details.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585. To attend, please notify Ms. Brenda Edwards at (202) 586–2945. Further attendance instructions can be found in section V, "Public Participation."

Instructions: All comments submitted must identify the NOPR for Test Procedures for Commercial Water Heating Equipment, and provide docket number EERE–2014–BT–TP–0008 and/or regulatory identification number (RIN) 1904–AD18. Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments by any of the following methods:

- *Email: CommWaterHeatingEquip2014TP0008@ee.doe.gov.* Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.
- *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

DOE will not accept telefacsimilies (faxes). For detailed instructions on submitting comments and additional information on the rulemaking process, see section V of this document (Public Participation).

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket Web page can be found at: *http://www.regulations.gov/#!docketDetail;D=EERE-2014-BT-TP-0008.* This Web page contains a link to the docket for this rulemaking on the *www.regulations.gov* site. The *www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket. See section V, "Public Participation," for further information on how to submit comments through *www.regulations.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT:

Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–6590. Email: *Ashley.Armstrong@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9507. Email: *Eric.Stas@hq.doe.gov.*

For more information on how to submit a comment, or review other public comments and the docket, contact Ms. Brenda Edwards, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–2945. Email: *Brenda.Edwards@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE intends to incorporate by reference the following industry standards into part 431:

(1) Gas Appliance Manufacturers Association (GAMA) Standard IWH–TS–1, March 2003 edition, "Method to Determine Performance of Indirect-Fired Water Heaters," sections 4, 5, 6.0, and 6.1;

(2) American National Standards Institute (ANSI) Standard Z21.10.3–2015/Canadian Standards Association (CSA) Standard 4.3–2015, "Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous," annex E.1;

(3) ANSI/American Society of Heating Refrigeration and Air-Conditioning Engineers (ASHRAE) Standard 118.1–2012, "Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water-Heating Equipment";

(4) ASTM International (ASTM) C177–13, "Standard Test Method for

Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus";

(5) ASTM C518–10, "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus;" and

(6) ASTM D2156–09, "Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels."

Copies of GAMA IWH–TS–1, March 2003 edition, can be obtained from the Air-conditioning, Heating, and Refrigeration Institute (AHRI), 2111 Wilson Blvd., Suite 500, Arlington, VA 22201, (703) 524–8800, or by going to *http://www.ahrinet.org/App_Content/ahri/files/standards%20pdfs/Indirect-Fired%20Water%20Heater%20Testing%20Standard03.pdf.*

Copies of ANSI Z21.10.3–2015/CSA 4.3–2015 and ANSI/ASHRAE 118.1–2012 can be obtained from the American National Standards Institute, 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4800, or by going to *http://webstore.ansi.org/.*

Copies of ASTM C177–13, ASTM C518–10, and ASTM D2156–09 can be obtained from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, (610) 832–9585, or by going to *http://www.astm.org/Standard/index.html.*

See IV.M. for a further discussion of these standards.

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I. Authority and Background

Title III, Part C[1] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6311–6317, as codified), added by Public Law 95–619, Title IV, section 441(a), sets forth a variety of provisions designed to improve energy efficiency.[2] It established the "Energy Conservation Program for Certain Industrial Equipment," a program covering certain commercial and industrial equipment (hereafter referred to as "covered equipment"), which includes the commercial water heating (CWH) equipment that is the subject of this rulemaking. (42 U.S.C. 6311(1)(K)) Title III, Part B[3] of EPCA (42 U.S.C. 6291–6309, as codified) sets forth a variety of provisions designed to improve energy efficiency and established the Energy Conservation Program for Consumer Products Other Than Automobiles. This includes consumer water heaters, which are also addressed in this rulemaking. (42 U.S.C. 6292(a)(4))

Under EPCA, energy conservation programs generally consist of four parts: (1) Testing; (2) labeling; (3) establishing Federal energy conservation standards; and (4) certification and enforcement procedures. The testing requirements consist of test procedures that manufacturers of covered products and equipment must use as both the basis for certifying to DOE that their products and equipment comply with the applicable energy conservation standards adopted pursuant to EPCA, and for making representations about the efficiency of that equipment. (42 U.S.C. 6293(c); 42 U.S.C. 6295(s); 42 U.S.C. 6314; 42 U.S.C. 6316)

The initial test procedures for CWH equipment were added to EPCA by the Energy Policy Act of 1992 (EPACT 1992), Public Law 102–486, and correspond to those referenced in ASHRAE and Illuminating Engineering Society of North America (IESNA) Standard 90.1–1989 (*i.e.,* ASHRAE Standard 90.1–1989) which went into effect on October 24, 1992. (42 U.S.C. 6314(a)(4)(A)) EPCA requires that if an industry test procedure that is referenced in ASHRAE Standard 90.1 is amended, DOE must amend its test procedure to be consistent with the amended industry test procedure, unless DOE determines that the amended test procedure is not reasonably designed to produce test results that reflect the energy efficiency, energy use, or estimated operating costs of the equipment during a representative average use cycle. In addition, DOE must determine that the amended test procedure is not unduly burdensome to conduct. (42 U.S.C. 6314(a)(2), (3) and (4)(B))

If DOE determines that a test procedure amendment is warranted, it must publish a proposed test procedure in the **Federal Register** and offer the public an opportunity to present oral and written comments. (42 U.S.C. 6314(b)(1)–(2)) When amending a test procedure, DOE must determine to what extent, if any, the proposed test procedure would alter the equipment's energy efficiency as determined under the existing test procedure. (42 U.S.C. 6293(e); 42 U.S.C. 6314(a)(4)(C))

The Energy Independence and Security Act of 2007 (EISA 2007), Public Law 110–140, amended EPCA to require that at least once every 7 years, DOE must review test procedures for each type of covered equipment, including CWH equipment, and either: (1) Amend the test procedures if the Secretary determines that the amended test procedures would more accurately or fully comply with the requirements of 42 U.S.C. 6314(a)(2)–(3),[4] or (2) publish a notice of determination not to amend a test procedure. (42 U.S.C. 6314(a)(1)(A)) Under this requirement, DOE must review the test procedures for CWH equipment no later than May 16, 2019, which is 7 years after the most recent final rule amending the Federal test method for CWH equipment.[5] The final rule resulting from this rulemaking will satisfy the requirement to review the test procedure for CWH equipment within 7 years.

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[1] For editorial reasons, Part C was codified as Part A–1 in the U.S. Code.

[2] All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015 (EEIA 2015), Public Law 114–11 (April 30, 2015).

[3] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

DOE's test procedure for CWH equipment is found at 10 CFR 431.106, *Uniform test method for the measurement of energy efficiency of commercial water heaters and hot water supply boilers (other than commercial heat pump water heaters)*.[6] DOE's test procedure for CWH equipment provides a method for determining the thermal efficiency and standby loss of CWH equipment. In a direct final rule for test procedures for CWH equipment, DOE incorporated by reference certain sections of the ANSI Standard Z21.10.3–1998 (ANSI Z21.10.3–1998), *Gas Water Heaters, Volume III, Storage Water Heaters With Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous.* 69 FR 61974, 61983 (Oct. 21, 2004). On May 16, 2012, DOE published a final rule for certain commercial heating, air-conditioning, and water-heating equipment in the **Federal Register** that, among other things, updated the test procedures for certain CWH equipment by incorporating by reference ANSI Z21.10.3–2011. 77 FR 28928, 28996. These updates did not materially alter DOE's test procedure for CWH equipment.

The American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210, was signed into law on December 18, 2012, and amended EPCA to require that DOE publish a final rule establishing a uniform efficiency descriptor and accompanying test methods for consumer water heaters and certain CWH equipment. (42 U.S.C. 6295(e)(5)) AEMTCA required DOE to replace the current efficiency metric for consumer water heaters (energy factor) and the current efficiency metrics for commercial water heaters (thermal efficiency and standby loss) with a uniform efficiency descriptor. (42 U.S.C. 6295(e)(5)(C)) Further, AEMTCA required that the uniform efficiency descriptor and accompanying test method apply, to the maximum extent possible, to all water heating technologies currently in use and to future water heating technologies. (42 U.S.C. 6295(e)(5)(H)) However, AEMTCA allowed DOE to exclude from the uniform efficiency descriptor, specific categories of covered water heaters that do not have residential uses, that can be clearly described, and that are effectively rated using the current thermal efficiency and standby loss descriptors. (42 U.S.C. 6295(e)(5)(F))

DOE published a final rule for test procedures for certain CWH equipment on July 11, 2014 ("July 2014 final rule"). 79 FR 40542. The final rule modified the current consumer water heater metric (energy factor) to create uniform energy factor (UEF), the descriptor to be used as the uniform efficiency descriptor for all consumer water heaters and certain CWH equipment that have residential uses. *Id.* at 40544. The final rule excluded certain CWH equipment from the uniform descriptor equipment that has no residential use, that can be clearly identified and described, and that are effectively rated using the current thermal efficiency and standby loss efficiency descriptors. In the July 2014 final rule, DOE defined and adopted a new test method for "residential-duty commercial water heaters," which are commercial water heaters that have residential uses. *Id.*

In this rulemaking for CWH equipment test procedures, DOE only considers amended test procedures for the CWH equipment classes that do not have residential applications and that are not "residential-duty commercial water heaters" as adopted in the July 2014 final rule.[7] On February 27, 2014, DOE published in the **Federal Register** a request for information (February 2014 RFI) to seek public comments on several issues associated with the current test procedure for CWH equipment. 79 FR 10999. DOE accepted comments and information on the February 2014 RFI until March 31, 2014, and considered all feedback received when developing the proposals contained in this rulemaking. Each of the issues raised in the February 2014 RFI is discussed in detail in section III, along with comments received on the issues and DOE's responses. In addition, several topics not addressed in the February 2014 RFI but brought up by interested parties in their comments are discussed in section III of this NOPR.

In support of its rulemaking effort, DOE typically seeks comments from the public and uses them to conduct in-depth technical analyses of publicly-available test standards and other relevant information. As noted above, this NOPR discusses the comments received by DOE in response to the February 2014 RFI and summarizes all proposed updates and amendments to the current test procedure. In its efforts to continually engage the public and interested parties in the rulemaking process, DOE seeks data and public input on all aspects of this rulemaking, in order to improve the testing methodologies, to accurately reflect commercial use, and to produce repeatable results. DOE also requests feedback from interested parties and stakeholders on the proposed amendments to the current test procedures for CWH equipment.

II. Synopsis of the Notice of Proposed Rulemaking

The February 2014 RFI raised several issues regarding the thermal efficiency and standby loss test methods for CWH equipment. Several other issues which were not part of the RFI were brought up through stakeholder feedback and comments on the RFI. In this NOPR, DOE discusses all issues identified by DOE and interested parties, and proposes to modify the current test procedures based on these issues, as necessary, in order to improve the consistency and accuracy of test results generated using the DOE test procedure while minimizing test burden.

As provided in 10 CFR 431.105, the current DOE test procedure incorporates by reference the ANSI Z21.10.3–2011 test method for use in 10 CFR 431.106, and that latter provision specifically directs one to follow Exhibits G.1 and

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[4] 42 U.S.C. 6314(a)(2) requires that test procedures be reasonably designed to produce test results which reflect energy efficiency, energy use, and estimated operating costs of a type of industrial equipment (or class thereof) during a representative average use cycle (as determined by the Secretary), and not be unduly burdensome to conduct.

42 U.S.C. 6314(a)(3) requires that if the test procedure is a procedure for determining estimated annual operating costs, such procedure must provide that such costs are calculated from measurements of energy use in a representative average-use cycle (as determined by the Secretary), and from representative average unit costs of the energy needed to operate such equipment during such cycle. The Secretary must provide information to manufacturers of covered equipment regarding representative average unit costs of energy.

[5] DOE published a final rule in the **Federal Register** on May 16, 2012, that, in relevant part, amended its test procedure for commercial water-heating equipment. 77 FR 28928.

[6] DOE has reserved a place in its regulations for a test procedure for commercial heat pump water heaters at 10 CFR 431.107, *Uniform test method for the measurement of energy efficiency for commercial heat pump water heaters.*

[7] Although DOE did not consider amended test procedures for residential-duty commercial water heaters, DOE proposes to amend the definitions pertaining to these equipment, as discussed in section III.F.3.

G.2 of the industry test procedure. In 2013, ANSI updated its test method and released a more recent version, *i.e.*, ANSI Z21.10.3–2013/Canadian Standards Association (CSA) 4.3–2013, *Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous* (hereinafter referred to as "ANSI Z21.10.3–2013"). In the February 2014 RFI, DOE stated its plan to amend its test procedure to reference ANSI Z21.10.3–2013, the updated industry test method for measuring thermal efficiency and standby loss. 79 FR 10999, 11001–11002 (Feb. 27, 2014). However, since publication of the February 2014 RFI, ANSI updated its test method twice. First, an updated version was approved on July 2, 2014, and released in August 2014, specifically, ANSI Z21.10.3–2014/CSA 4.3–2014, *Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous* (hereinafter referred to as "ANSI Z21.10.3–2014"). Another updated version was then approved on October 5, 2015, and released in November 2015, specifically, ANSI Z21.10.3–2015/CSA 4.3–2015, *Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous* (hereinafter referred to as "ANSI Z21.10.3–2015"). DOE is proposing to incorporate by reference annexes E.1 of this latest industry test procedure (ANSI Z21.10.3–2015) for measuring thermal efficiency and standby loss.

After a careful review of ANSI Z21.10.3–2015, DOE found one significant difference between the sections of the test standard that are currently referenced by DOE (*i.e.*, Exhibits G.1 and G.2 of ANSI Z21.10.3–2011) and those contained in ANSI Z21.10.3–2015 (*i.e.*, Annexes E.1 and E.2). This difference is in the temperature differential terms used in the equations to calculate standby loss in Annex E.2 of ANSI Z21.10.3–2015 and Exhibit G.2 of ANSI Z21.10.3–2011. The equations in Annex E.2 of ANSI Z21.10.3–2015 and Exhibit G.2 of ANSI Z21.10.3–2011 are meant to calculate standby loss, which is defined as the average hourly energy required to maintain the stored water temperature expressed as a percentage of the total heat content of the stored water above room temperature. However, the temperature differential term used in the denominator of the standby loss equation in Annex E.2 of ANSI Z21.10.3–2015 does not represent the total heat content of the water heater. Therefore, DOE has tentatively concluded that it is appropriate to use the standby loss equation in Exhibit G.2 of ANSI Z21.10.3–2011, which is both accurate and best represents the standby loss expressed as a percentage per hour of the total heat content of the stored water above room temperature. Therefore, DOE proposes to include the equation for standby loss 'S' presented in Exhibit G.2 of ANSI Z21.10.3–2011 in the DOE test procedure for all covered commercial storage water heaters and storage-type instantaneous water heaters (see section III.F for discussion on DOE's proposed definition for "storage-type instantaneous water heater"). However, for instantaneous water heaters and hot water supply boilers other than storage-type instantaneous water heaters, DOE proposes separate standby loss test procedures and equations, as discussed in sections III.G and III.I. DOE did not find any other significant differences between Annexes E.1 and E.2 of ANSI Z21.10.3–2015 and Exhibits G.1 and G.2 of ANSI Z21.10.3–2011. Therefore, other than the reference for the standby loss equation, DOE proposes to update the reference in its test procedures for CWH equipment (as applicable) to the most recent version of the industry test standard. Specifically, DOE proposes to incorporate by reference Annex E.1 of ANSI Z21.10.3–2015. This issue is further discussed in section III.A of this rulemaking.

DOE's current test procedure for oil-fired CWH equipment at 10 CFR 431.106 also refers to ASTM Standard D2156–80 ("ASTM D2156–80"), "Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels." Specifically, this industry method is cited to determine that smoke in the flue does not exceed a No. 1 smoke spot number. A more recent version of this standard, ASTM Standard D2156–09 ("ASTM D2156–09"), "Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels," was approved in 2009 and reapproved in 2013. DOE carefully reviewed the two versions of this industry method and identified no significant differences that would affect the determination of smoke spot number as referred to in DOE's test procedure. Therefore, DOE proposes to incorporate by reference ASTM D1256–09 for the purpose of determining the smoke spot number.

However, DOE also proposes clarifications to the procedure for determining the smoke spot number. First, DOE proposes to clarify that the smoke spot number must be determined prior to taking measurements for the efficiency tests (*i.e.*, the thermal efficiency test or standby loss test). Specifically, for the thermal efficiency test, DOE proposes to require that the smoke spot number be determined after a steady-state condition has been reached but before beginning measurements for the thermal efficiency test. For the standby loss test, DOE proposes to require that the smoke spot number be determined after the first cut-out before beginning measurements for the standby loss test. However, DOE proposes not to require that the smoke spot test be conducted prior to beginning an efficiency test (*i.e.*, thermal efficiency or standby loss) if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test. DOE also proposes that the requirements for when to conduct the smoke spot test also apply to measurement of the CO_2 reading, which is required by DOE's current test procedures for oil-fired CWH equipment at 10 CFR 431.106. Second, DOE proposes to require that the smoke measuring device be connected to an open-ended tube that projects into the flue ¼ to ½ of the pipe diameter. This proposed clarification regarding the smoke measuring device is based on the requirements for commercial space-heating boilers in the ANSI/AHRI Standard 1500 ("AHRI 1500–2015"), "2015 Standard for Performance Rating of Commercial Space Heating Boilers." Because this requirement comes from an industry-accepted test method, DOE expects this requirement to lead to minimal test burden for manufacturers and would simply serve to clarify the test set-up.

DOE's current definition for "R-value" at 10 CFR 431.102 references two industry test methods: (1) ASTM Standard Test Method C177–97 ("ASTM C177–97"), "Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus"; and (2) ASTM Test Standard C518–91 ("ASTM C518–91"), "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus." More recent versions of ASTM C177 and ASTM C518 were published in October 2013 and June 2010, respectively: (1) ASTM Standard Test Method C177–13 ("ASTM C177–13"), "Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus"; and (2) ASTM Test

Standard C518–10 ("ASTM C518–10"), "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus." After careful review, DOE has tentatively concluded that there are no substantive differences in the procedures for measuring R-value between the two versions of ASTM C177 or between the two versions of ASTM C518. Based upon its analysis, DOE proposes to incorporate by reference ASTM Standard Test Methods C177–13 and C518–10 and update its references to these versions in the definition for "R-value" at 10 CFR 431.102, in order to maintain up-to-date references to industry test methods.

Among the comments received by DOE on the published RFI, several commenters raised concerns with regards to the repeatability of the standby loss test method as set forth in the current DOE test method (which references Exhibit G.2 of ANSI Z21.10.3–2011). To address these concerns of test repeatability, DOE proposes several improvements to both the thermal efficiency and standby loss test methods, which are discussed in detail in section III.B of this rulemaking.

Unfired hot water storage tanks are covered equipment included in the scope of this rulemaking. These tanks store hot water and do not consume fuel or electricity for the purpose of heating water, so any energy efficiency improvements would target standby loss associated with heat loss from the stored water. Currently, unfired hot water storage tanks are required to have thermal insulation with a minimum thermal resistance (R-value) of 12.5 °F·ft^2·hr/Btu. *See* 10 CFR 431.110. In the February 2014 RFI, DOE requested comment on whether the R-value requirement was an appropriate energy efficiency descriptor and whether it should adopt a standby loss test and metric to replace the current R-value requirement. DOE also noted that determining the R-value of a single sample does not assess whether this value is applicable to the entire tank surface area, including bottom, top, and fitting areas. 79 FR 10999, 11002 (Feb. 27, 2014). After considering public comments from stakeholders and interested parties, DOE proposes to adopt a standby loss test for unfired storage tanks that is based, in part, on existing industry test methods (*i.e.*, GAMA Testing Standard IWH–TS–1 (March 2003 edition)). Energy conservation standards for unfired hot water storage tanks will remain in terms of the current insulation R-value requirement until DOE completes a future rulemaking to establish standards in terms of the proposed standby loss metric, presuming such metric is adopted in the test procedure final rule. This proposed standby loss test method is discussed in detail in section III.C.

Another issue raised by DOE in the February 2014 RFI regarded the method of setting the tank thermostat prior to conducting the thermal efficiency test. 79 FR 10999, 11002–03 (Feb. 27, 2014). The current Federal test procedure at 10 CFR 431.106 references Exhibits G.1 and G.2 of ANSI Z21.10.3–2011, which requires water heaters to achieve a maximum mean tank temperature of 140 °F ± 5 °F after the thermostat reduces the gas supply to a minimum. However, some CWH equipment may experience difficulty in attaining a mean tank temperature of 140 °F ± 5 °F due to the design of the heat exchanger and positioning of the thermostat sensor. Such systems may in fact be able to supply water at a temperature of 140 °F ± 5 °F, but yet not meet the mean tank temperature requirement. As a result, DOE proposes to modify the test procedure for gas-fired and oil-fired storage water heaters and storage-type instantaneous water heaters to use the outlet water temperature as the set point for setting the thermostat, rather than the mean tank temperature. This change would still ensure the water heater provides water at the specified temperature, while accommodating models that are not designed to have high mean tank temperatures (*i.e.*, condensing water heaters) or that rely upon stratification. The set point temperature value would remain the same at 140 °F ± 5 °F. However, for electric storage water heaters, DOE proposes to maintain a mean tank temperature requirement for the standby loss test because of complications with setting the thermostats for each electric heating element. Specifically, it is unclear how each thermostat could be set to provide a designated outlet water temperature in a way that would differ from the method used for a mean tank temperature requirement. Additional discussion of this issue is contained in section III.D.

In the February 2014 RFI, DOE requested information on whether any clarifications are needed in the thermal efficiency test procedure to indicate water flow requirements or to account for changes in thermal energy stored within the water heater during the duration of the test. 79 FR 10999, 11003 (Feb. 27, 2014). Based on the comments received, DOE has tentatively concluded that the current test procedure prescribed in 10 CFR 431.106 does not require any amendment to account for changes in stored thermal energy or water flow requirements during the thermal efficiency test method. The existing test procedure requires the water heater to attain steady-state conditions with no variation of outlet water temperature in excess of 2 °F over a period of 3 minutes. Once steady-state conditions are achieved, the internal tank temperature maintains a constant value, indicating that the stored energy in the water heater remains constant as long as the firing rate remains constant. While DOE has tentatively concluded that an amendment to account for stored energy changes is not needed, DOE proposes to introduce a statement clarifying that during the thermal efficiency test, the burner must continuously fire at the full firing rate (*i.e.*, no modulation or cut-outs) for the entire duration of the thermal efficiency test, and the outlet water temperature must be maintained at 70 °F ± 2 °F above the supply water temperature. DOE also proposes to clarify that during the thermal efficiency and standby loss tests, no settings on the water heating equipment can be changed until measurements for the test have finished. Additional discussion of these issues is contained in section III.E.

In this NOPR, DOE proposes several changes to the definitions included in the regulations for consumer water heaters at 10 CFR 430.2 and for CWH equipment at 10 CFR 431.102. For consumer water heaters, DOE proposes to remove exemptions from the definitions that exclude units that heat water to temperatures greater than 180 °F and units with a storage capacity greater than 120 gallons. DOE also proposes to remove the definitions for consumer "electric heat pump water heater" and "gas-fired heat pump water heater." DOE proposes the following changes to the definitions for CWH equipment: (1) Replacing all mentions of the terms "input rating" or "rated input" with the term "fuel input rate" in the context of gas-fired or oil-fired CWH equipment, based on the proposed changes regarding fuel input rate that are further discussed in section III.K; (2) modifying DOE's definitions for "instantaneous water heater" and "storage water heater" by adding the input criteria that separate consumer water heaters and commercial water heaters and removing several phrases that do not serve to clarify coverage of units under the definitions; and (3) removing the definition of "packaged boiler." DOE also proposes to modify the definition for "residential-duty commercial water heater" by removing from its scope the following classes, for which the input criteria indicating residential application do not allow classification of any units: electric storage water heaters, heat pump water heaters with storage, gas-fired instantaneous water heaters, and oil-fired instantaneous water heaters. Additional discussion of these proposed changes to DOE's definitions for consumer water heaters and CWH equipment is provided in section III.F.

Water heaters with storage tanks and submerged fire-tube heat exchangers that have input ratings above 4,000 Btu/h per gallon of water stored are currently classified as instantaneous water heaters and hot water supply boilers with a storage volume greater than or equal to 10 gallons. However, DOE believes that these units that are equipped with storage tanks are fundamentally different from other instantaneous water heaters, and, therefore, the Department proposes to define the term "storage-type instantaneous water heater." DOE also proposes that such units would be tested according to the same method as used for commercial storage water heaters. Additional discussion of these issues are contained in section III.F.4.

Instantaneous water heaters and hot water supply boilers are covered equipment subject to the current Federal test procedure as set forth in 10 CFR 431.106. In response to the February 2014 RFI, AHRI raised an issue with regards to the applicability of the standby loss test procedure described in Exhibit G.2 of ANSI Z21.10.3–2011 for instantaneous water heaters and hot water supply boilers that have no means of initiating burner operation without an active flow of water through the equipment. Additionally, ANSI Z21.10.3–2015 was updated from previous versions of the industry testing standard to include a new test method for measuring the standby loss of tube-type instantaneous water heaters, which AHRI recommended DOE use for determining the standby loss of such instantaneous water heaters and hot water supply boilers. DOE identified numerous problematic issues with this procedure and tentatively decided not to incorporate it by reference in its test procedures for CWH equipment. (The AHRI comments and this test method are discussed it in greater detail, along with DOE's proposed standby loss test procedure for flow-activated instantaneous water heaters, in section III.G.) The current standby loss test procedure involves shutting off the flow of water through the water heater and calculating the amount of energy required to raise the internally stored water temperature to a thermostatically-set value when it drops to a point at which it needs to be reheated. For such a test, it is assumed that when the stored water reaches the minimum allowable water temperature (below the thermostat set point) a control signal activates that will initiate the next firing or heating cycle. This is true for most CWH equipment; however, flow-activated instantaneous water heaters require flow of water through the heater to initiate the next firing or heating cycle. In these designs, if there is no continuous water flow, the next firing or heating cycle is not triggered even if the temperature of hot water inside the heater falls below the thermostat set point. To address this issue, DOE proposes to adopt a separate standby loss test for flow-activated instantaneous water heaters. DOE currently only prescribes standby loss standards for gas-fired and oil-fired instantaneous water heater and hot water supply boilers with a storage capacity greater than or equal to 10 gallons. The proposed test method would apply to all units that meet the proposed definition for "flow-activated instantaneous water heater," and is described in detail in section III.G.

The current thermal efficiency and standby loss test method requires the water heater to be set up as per Figure 2 in ANSI Z21.10.3–2011, which is identical to Figure 3 in ANSI Z21.10.3–2015. Although the figures provide an unscaled pictorial arrangement of the test set up, neither Figure 2 in ANSI Z21.10.3–2011 nor Figure 3 in ANSI Z21.10.3–2015 specifies the exact location of the outlet water temperature measurement. DOE understands that this unspecified location for outlet water temperature measurement could lead to inconsistent test results and an inaccurate representation of the actual outlet water temperature, especially if the outlet water temperature represents the internal stored water temperature for instantaneous water heaters and hot water supply boilers (as proposed in this NOPR and discussed in section III.G and III.I). Moreover, the temperature-sensing installations, as set forth in Annex E.1 of ANSI Z21.10.3–2015, do not provide clear instructions for installing temperature-sensing means for instantaneous water heaters and hot water supply boilers. Considering the issues related to temperature measurement for instantaneous water heaters and hot water supply boilers, DOE proposes to specify the temperature-sensing location for the outlet water temperature such that the tip or junction of the sensor is less than or equal to 5 inches away from the water heater jacket and requirements for placement of the temperature-sensing probe in the water line for both supply and outlet water measurement. In addition to this issue, DOE also proposes to add supply and outlet water valves at locations closer to the water heater. Specifically, DOE proposes to add a supply water valve within a distance of 5 inches from the water heater jacket and an outlet water valve within a distance of 10 inches from the water heater jacket. Currently, the test set up does not clearly indicate the location of the water supply valves. These valves would be turned off at the start of the standby loss test for instantaneous water heaters and hot water supply boilers (as proposed in this NOPR and discussed in section III.G and III.I). DOE also proposes to add provisions for outlet water temperature measurement and placement of water valves for instantaneous water heaters and hot water supply boilers that have multiple supply and outlet water connections and that are shipped with piping installed by the manufacturer. Finally, DOE proposes to clarify the conditions for using a re-circulating loop. The proposed provisions are similar to those specified in ANSI Z21.10.3–2011 (and ANSI Z21.10.3–2015), and further details on this issue are contained in section III.H.

In response to the RFI, manufacturers also raised the issue of the applicability of the current Federal standby loss test procedure to instantaneous water heaters and hot water supply boilers that are not tank-type water heaters and that have a storage capacity of ten gallons or more (all comments on this topic are discussed in section III.I of this NOPR). The Federal standby loss test procedure in 10 CFR 431.106 incorporates by reference Exhibit G.2 of ANSI Z21.10.3–2011, which requires the measurement of mean tank temperature to calculate standby loss. Instantaneous water heaters and hot water supply boilers generally are not equipped with an integral storage tank, but rather the stored water is contained within the heat exchanger. Therefore, measuring the mean tank temperature for such type of equipment would not be possible (as a storage tank does not exist). Moreover, due to the complex geometry and design of the heat exchangers of such equipment, obtaining an accurate value of the mean stored water temperature inside the heat exchanger would be difficult, or in some cases, may be impossible. To address this issue, DOE proposes to use the outlet water temperature as a conservative estimate for the mean tank temperature. This approach is similar to that used for the standby loss test for flow-activated water heaters and would be significantly less burdensome than using other means to accurately measure the stored water temperature inside the heat exchanger. Additional details on this test procedure are provided in section III.I.

In the February 2014 RFI, DOE also requested comments on development of a test procedure for commercial heat pump water heaters (CHPWHs). 79 FR 10999, 11003 (Feb. 27, 2014). Based on the comments received, DOE proposes to incorporate by reference ANSI/ASHRAE Standard 118.1–2012, *Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water-Heating Equipment* (ANSI/ASHRAE Standard 118.1–2012) to use as the basis for the Federal CHPWH test method, with several modifications discussed in further detail in III.J. DOE also proposes to adopt rating conditions for four categories of CHPWHs: (1) Air-source CHPWHs; (2) direct geo-exchange CHPWHs; (3) ground water-source CHPWHs; and (4) indoor water-source CHPWHs. The proposed rating conditions are based on ANSI/AHRI Standard 1300 (I–P)–2013: *Performance Rating of Commercial Heat Pump Water Heaters*. Additional discussion of this proposed test procedure is contained in section III.J.

In its current regulations for CWH equipment in subpart G to 10 CFR part 431, DOE includes several terms referring to the input capacity, and does not include any method for determining or verifying the input capacity during testing. In this NOPR, DOE proposes to define "fuel input rate" for gas-fired and oil-fired CWH equipment and proposes a procedure for calculating the fuel input rate during the thermal efficiency test. DOE proposes that the gas consumption be measured every 10 minutes, and that the calculated fuel input rates for each 10-minute interval of the thermal efficiency test cannot vary by more than ± 2 percent between each reading. DOE also proposes means to verify the fuel input rate. Additional discussion of these proposed changes regarding fuel input rate is contained in section III.K.

In this NOPR, DOE proposes several changes to its certification requirements at 10 CFR part 429. First, DOE proposes to add requirements to 10 CFR 429.44 that manufacturers must certify whether gas-fired and oil-fired instantaneous water heaters and hot water supply boilers contain submerged heat exchangers, so that such models can be classified under DOE's proposed definition for "storage-type instantaneous water heaters." Second, DOE proposes to require manufacturers to certify whether instantaneous water heaters and hot water supply boilers require flow through the water heater to initiate burner ignition. Further discussion of these proposed changes are included in section III.M. Additionally, DOE proposes default values for these parameters to be used in testing if the parameters are not reported in manufacturer literature shipped with the equipment or the supplemental test instructions. Further discussion of these proposed default values are included in section III.L.

In any rulemaking to amend a test procedure, DOE must determine to what extent, if any, the proposed test procedure would alter the measured energy efficiency of any covered product as determined under the existing test procedure. (42 U.S.C. 6293(e)(1); 42 U.S.C. 6314(a)(4)(C)) DOE expects that the proposed changes to the test procedure will not significantly alter the efficiency ratings for a most classes of CWH equipment. There could, however, be changes to the measured energy efficiency for unfired hot water storage tanks. If DOE adopts the changes to the existing test procedures proposed in this NOPR for those products, then DOE will establish energy conservations standards for unfired hot water storage tanks in terms of a new standby loss metric in a separate rulemaking, and the test procedure changes related to unfired hot water storage tanks will not apply until compliance is required with the new standards. DOE also proposes a new test procedure for measuring standby loss of flow-activated instantaneous water heaters with a storage capacity greater than or equal to 10 gallons. However, DOE does not believe this proposed test procedure will affect the measured energy efficiency of flow-activated instantaneous water heaters.

III. Discussion

In response to the February 2014 RFI, DOE received eight written comments from the following interested parties: Bradford White Corporation (Bradford White); A.O. Smith Corporation (A.O. Smith); HTP, Inc. (HTP); Rheem Manufacturing Company (Rheem); Edison Electric Institute (EEI); Air-Conditioning, Heating, and Refrigeration Institute (AHRI); American Public Power Association (APPA); and the American Council for an Energy-Efficient Economy (ACEEE) and National Resources Defense Council (NRDC), who filed a joint comment (henceforth referred to as "Joint Advocates"). These interested parties commented on a range of issues, including those identified by DOE in the February 2014 RFI, as well as several other pertinent issues. The issues, the comments received, DOE's responses to those comments, and the resulting proposed changes to the test procedures for CWH equipment, are discussed in the following subsections.

Updated Industry Test Methods

DOE's test procedure for measuring the energy efficiency for CWH equipment currently incorporates by reference the industry standard ANSI Z21.10.3–2011 at 10 CFR 431.105. Additionally, DOE lists ASTM Standard Test Methods D2156–80, C177–13, and C518–10 as sources of information and guidance in 10 CFR 431.104. DOE defines "ASTM Standard Test Method D2156–80" at 10 CFR 431.102, and points to this source in DOE's current test procedure at 10 CFR 431.106. DOE points to ASTM C177–13 and ASTM C518–10 in its definition for "R-value" at 10 CFR 431.102. The following subsections discuss proposed revisions to DOE's test procedure for CWH equipment vis-à-vis these industry standards.

1. ANSI Z21.10.3 Testing Standard

As noted above, DOE's test procedure for measuring the energy efficiency for CWH equipment currently incorporates by reference the industry standard ANSI Z21.10.3–2011 at 10 CFR 431.105. Specifically, the DOE test procedures at 10 CFR 431.106 directs one to follow Exhibits G.1 and G.2 of ANSI Z21.10.3–2011 for measuring thermal efficiency and standby loss, respectively. An updated edition of the industry test method, ANSI Z21.10.3–2013/CSA 4.3–2013, was approved on March 25, 2013, and released in July 2013.

In the February 2014 RFI, DOE requested feedback on the appropriateness of replacing references to ANSI Z21.10.3–2011 with equivalent references to ANSI Z21.10.3–2013 (which, at that time, was the most current industry testing standard). 79 FR 10999, 11001–02 (Feb. 27, 2014). All parties that commented on this issue agreed with DOE that ANSI Z21.10.3–2013 was an appropriate replacement for ANSI Z21.10.3–2011. (Bradford White, No. 8 at p. 1;[8] Rheem, No. 3 at p. 1; HTP, No. 5 at pp. 1–2; A.O. Smith,

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[8] A notation in this form provides a reference for information that is in the docket of DOE's rulemaking to develop test procedures for commercial water heating equipment (Docket No. EERE–20014–BT–TP–0008), which is maintained at *www.regulations.gov*. This notation indicates that the statement preceding the reference is document number 8 in the docket for the test procedure rulemaking for commercial water heating equipment, and appears at page 1 of that document.

No. 7 at p. 1; Joint Advocates, No. 4 at p. 1; and AHRI, No. 2 at p. 1)

However, since publication of the February 2014 RFI, ANSI updated its test method twice. First, an updated version was approved on July 2, 2014, and released in August 2014—ANSI Z21.10.3–2014/Canadian Standards Association (CSA) 4.3–2014, *Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous* (hereinafter referred to as "ANSI Z21.10.3–2014"). Another updated version was then approved on October 5, 2015, and released in November 2015—ANSI Z21.10.3–2015/CSA 4.3–2015, *Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous* (hereinafter referred to as "ANSI Z21.10.3–2015"). DOE reviewed ANSI Z21.10.3–2015 and compared it with ANSI Z21.10.3–2011, and found one significant difference between the sections of the test method that DOE currently references in its test procedures for CWH equipment (*i.e.*, Exhibits G.1 and G.2 of ANSI Z21.10.3–2011) and those contained in ANSI Z21.10.3–2015 (*i.e.*, Annexes E.1 and E.2). In Exhibit G.2 of ANSI Z21.10.3–2011, the current DOE test procedure, the equation for standby loss 'S' is presented as:

$$S = \left\{ \left[\frac{(Cs)(Qs)(H) + Ec}{(K)(Va)(\Delta T_3)(t)} \right] - \left[\frac{\Delta T_4}{(\Delta T_3)(t)\left(\frac{E_t}{100}\right)} \right] \right\} \times 100$$

In Annex E.2 of ANSI Z21.10.3–2015, the equation is exactly the same, except that the $\Delta_3$term in the denominator of the second term of the equation is replaced by ΔT_4. Based on the definitions for the terms provided in both ANSI Z21.10.3–2011 and ANSI Z21.10.3–2015, ΔT_3 refers to the difference between the average value of the mean tank temperature and the average value of the ambient room temperature expressed in °F. The term ΔT_4 is defined as the difference between the final and the initial mean tank temperature.

DOE has tentatively concluded that the standby loss equation provided in ANSI Z21.10.3–2011 (and ANSI Z21.10.3–2013) is appropriate. If the ΔT_3 term is replaced with the ΔT_4 term in the second term of the standby loss equation as specified by ANSI Z21.10.3–2015, then the term ΔT_4 would cancel out, and the equation will not include the temperature difference between the final and initial mean tank temperature that corresponds to the heat lost by the water heater during the course of the test. Therefore, DOE proposes to adopt as part of appendices A and B to subpart G of part 431 the standby loss equation as specified in Exhibit G.2 of ANSI Z21.10.3–2011 (and also included in ANSI Z21.10.3–2013) for calculating the standby loss of all storage water heaters and storage-type instantaneous water heaters. DOE also proposes to re-arrange the terms of the equation to improve the readability of the equation, and remove the gas consumption term for electric water heaters. For instantaneous water heaters and hot water supply boilers other than storage-type instantaneous water heaters, DOE proposes separate standby loss test procedures and equations in sections III.G and III.I.

DOE did not find any other substantive differences between Exhibits G.1 and G.2 of ANSI Z21.10.3–2011 and Annexes E.1 and E.2 of ANSI Z21.10.3–2015. Therefore, DOE proposes to incorporate by reference Annex E.1 of ANSI Z21.10.3–2015 in its proposed test procedures for CWH equipment. DOE does not propose to incorporate by reference Annex E.2 of ANSI Z21.10.3–2015; however, DOE has included certain language from Annex E.2 in its standby loss test procedures proposed in this NOPR.

ANSI Z21.10.3–2015 also includes a new efficiency test procedure—Annex E.3, "Method of test for measuring standby loss for tube type instantaneous water heaters with 10 or greater gallons of storage." This procedure provides a method to test standby loss of instantaneous water heaters and hot water supply boilers, including those that require flow of water to activate the burner or heating element (*i.e.*, "flow-activated instantaneous water heaters"). DOE reviewed this test procedure, and it is discussed in further detail in section III.G, where DOE proposes a new standby loss test procedure for flow-activated instantaneous water heaters.

DOE also proposes a procedure similar to that specified in section 5.27 of ANSI Z21.10.3–2015 for determining the storage volume of CWH equipment. DOE's proposed language only includes clarifying differences from the language in section 5.27 of ANSI Z21.10.3–2015, and DOE believes that the clarifying differences would not affect conduct of the test procedure between DOE's proposed procedure and the method included in section 5.27 of ANSI Z21.10.3–2015. DOE's proposed procedure for determining storage volume is discussed in further detail in section III.G.

2. ASTM Standard Test Method D2156

DOE's current test procedure for oil-fired CWH equipment at 10 CFR 431.106 points to ASTM Standard Test Method D2156–80. Specifically, DOE requires that smoke in the flue does not exceed No. 1 smoke as measured by the procedure in ASTM D2156–80. However, there is a more recent version of ASTM D2156 that was approved on December 1, 2009, and reapproved on October 1, 2013. After careful review of D2156–80 and D2156–09, DOE has tentatively concluded that no substantive changes were made between these versions in the test method for determining the smoke spot number. Therefore, DOE proposes to incorporate by reference this newer version, ASTM D2156–09, in its test procedures for oil-fired CWH equipment, in appendices A, C, and E to subpart G of 10 CFR part 431.

DOE's current requirement for smoke spot number of flue gas for oil-fired CWH equipment requires that the smoke in the flue does not exceed No. 1 smoke, but does not specify when during the test to determine the smoke spot number. To improve consistency and repeatability of testing of CWH equipment, DOE is proposing to specify when to conduct the smoke spot test. DOE considered several options for this specification. The first option DOE considered would be to require determination of the smoke spot number after steady-state operation has been achieved, but prior to beginning measurement for the thermal efficiency test. The second option considered would be to require determination of the smoke spot number before and after conduct of the test. The third option considered would be to require determination of the smoke spot number before, after, and during the test. Specifically, in the third option, the smoke spot number would be determined during the thermal efficiency test 15 minutes after the beginning of the test. This is similar to the requirement to determine the smoke spot number every 15 minutes during the thermal efficiency and combustion efficiency tests that is specified for commercial space heating boilers in AHRI 1500–2015.

After considering these three options and the relative benefits and test burden they might provide, DOE has tentatively concluded that determining the smoke spot number prior to conduct of efficiency testing sufficiently assesses the combustion performance while minimizing test burden for manufacturers. DOE reasoned that it is unlikely for the smoke density to change to a significant extent during a steady-state test if the burner settings are maintained throughout the test. As discussed in section III.E, DOE is also proposing to add a clarifying statement to the test procedure stating that the settings on CWH equipment during the thermal efficiency test are not be changed once steady-state conditions have been established. Therefore, DOE has tentatively concluded that it is not necessary to require determination of the smoke spot number during or after efficiency testing, and rather proposes to require determination of the smoke spot number before beginning measurement for efficiency testing. Specifically, for the thermal efficiency test, DOE proposes to require determination of the smoke spot number after steady-state condition has been reached (as determined by no variation of outlet water temperature in excess of 2 °F over a 3-minute period). For the standby loss test, DOE proposes to require determination of the smoke spot number after the first cut-out before beginning measurements for the standby loss test. DOE also proposes to require that the CO_2 reading, which is required to be measured when testing oil-fired CWH equipment under DOE's current test procedures specified at 10 CFR 431.106, also be measured at the time required for determination of the smoke spot number.

DOE also proposes to clarify that the smoke spot test and measurement of CO_2 reading are required before conduct of the thermal efficiency test or standby loss test (as applicable) of oil-fired CWH equipment with one exception. DOE proposes that, if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test, a second smoke spot test or CO_2 reading is not required prior to beginning another efficiency test (*i.e.*, thermal efficiency or standby loss).

Additionally, to further clarify the appropriate method for determining the smoke spot number, DOE proposes to adopt specifications to the test procedure for the set-up for measuring the smoke density. Specifically, DOE proposes to require that the smoke measuring device be connected to an open-ended tube, and that this tube must project into the flue ¼ to ½ of the pipe diameter. These proposed requirements are from the same as those specified for commercial space-heating boilers in AHRI 1500–2015.

Issue 1: DOE seeks comment on its proposed incorporation by reference of ASTM D2156–09, and on its proposed additional specifications for how to set up the smoke spot test, and when to conduct the smoke spot test and measure the CO_2 reading.

3. ASTM Test Standards C177–13 and C518–10

DOE's current definition for "R-value" at 10 CFR 431.102 references two industry test methods: ASTM Standard Test Method C177–97 and ASTM Test Standard Method C518–91.

A more recent version of ASTM C177 was approved in September 2013 and published in October 2013 (ASTM C177–13). After careful review, DOE has tentatively concluded that there are no substantive differences in the procedures for measuring R-value between the two versions of ASTM C177. Additionally, a more recent version of ASTM C518 was approved in May 2010 and published in June 2010 (ASTM C518–10). After careful review, DOE has tentatively concluded that there are no substantive differences in the procedures for measuring R-value between the two versions of ASTM C518. Therefore, DOE proposes to incorporate by reference ASTM Standard Test Methods C177–13 and C518–10 and to update its references to these versions in the definition for "R-value" at 10 CFR 431.102.

Issue 2: DOE seeks comment on its proposed incorporation by reference of ASTM C177–13 and C518–10 for the definition of "R-value."

B. Test Method Repeatability and Ambient Test Conditions

As discussed in section III.A of this rulemaking, the DOE test procedure for CWH equipment currently incorporates by reference ANSI Z21.10.3–2011 at 10 CFR 431.105, and DOE proposes to incorporate by reference Annex E.1 of the updated version of the standard, ANSI Z21.10.3–2015, for measuring thermal efficiency and standby loss, respectively.

The test method for thermal efficiency of CWH equipment in Annex E.1 of ANSI Z21.10.3–2015 (and also in Exhibit G.1 of ANSI Z21.10.3–2011) requires that the thermostat be set so that the gas supply is reduced to a minimum, once the mean tank temperature reaches 140 °F ± 5 °F. Then water is supplied continuously to the water heater at a temperature of 70 °F ± 2 °F. The outlet water temperature is adjusted by varying the flow rate until the temperature is constant at 70 °F ± 2 °F above the supply water temperature. After the outlet water reaches steady state, water flow (measured by weight) is recorded for a 30-minute test period, along with supply and outlet water temperatures, the ambient room temperature, and fuel and electricity consumption. These data collected during the 30-minute test period are used to calculate the thermal efficiency.

The standby loss test method in Annex E.2 of ANSI Z21.10.3–2015 (and also in Exhibit G.2 of ANSI Z21.10.3–2011) stipulates that a commercial water heater must be set up as described for the thermal efficiency test and that the unit must be put into operation with the burner gas supply opened. After the first burner cut-out,[9] the unit is allowed to remain in standby mode until the second burner cut-out, at which point the collection of test data begins. Test data are recorded at 15 minute intervals, and the test ends at either the first cut-out after 24 hours have elapsed, or when 48 hours have elapsed, whichever occurs first. The ambient room temperature, mean tank temperature, fuel and electricity consumption, and time are measured during the test and used to calculate the standby loss.

In the February 2014 RFI, DOE requested information and data pertaining to the repeatability of thermal efficiency and standby loss test methods included in the ANSI Z21.10.3–2011 and ANSI Z21.10.3–2013 test methods. 79 FR 10999, 11001–02 (Feb. 27, 2014).

HTP commented that the thermal efficiency test is repeatable and is reasonably consistent between testing sites. (HTP, No. 5 at p. 2) No other interested parties provided information on the repeatability of the thermal efficiency test method in ANSI Z21.10.3.

Several parties provided comments regarding the repeatability of the standby loss test method. HTP commented that the standby loss test method produces data with significant lab-to-lab variation in test results and attributed this variation to the physics of the test and the ambient conditions of the test. HTP suggested investigating the effects of stipulating a maximum air draft in the test environment on repeatability of the standby loss test. (HTP, No. 5 at p. 2) HTP and AHRI commented that due to the small amount of energy consumption measured during the standby loss test, the error and variation associated with the tolerances of commercially-available test instrumentation has a larger influence on test results, resulting in a greater degree of variance for the standby loss test compared to the thermal efficiency test. (HTP, No. 5 at p. 2 and AHRI, No. 2 at p. 1)

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[9] By "burner cut-out," DOE refers to when the energy supply to a burner is reduced to a minimum.

Based on these comments from interested parties, DOE investigated various potential test procedure modifications to reduce the variability of results from the test procedures for thermal efficiency and standby loss. In addition, DOE conducted investigative testing that helped inform the proposals discussed in this NOPR. DOE proposes the following seven modifications to the current thermal efficiency and standby loss test procedures, after tentatively determining that these modifications would reduce variation in results: (1) Stipulating a maximum air draft requirement of 50 ft/min as measured prior to beginning the thermal efficiency or standby loss tests; (2) tightening the ambient room temperature tolerance from ±10.0 °F to ±5.0 °F and the allowed variance from mean ambient temperature from ±7.0 °F to ±2.0 °F; (3) requiring measurement of test air temperature—the temperature of entering combustion air—and requiring the test air temperature not vary by more than ±5 °F from the ambient room temperature at any measurement interval during the thermal efficiency and standby loss tests for gas-fired and oil-fired CWH equipment; (4) establishing a requirement for ambient relative humidity of 60 percent ±5 percent during the thermal efficiency and standby loss tests for gas-fired and oil-fired CWH equipment; (5) requiring a soak-in period prior to testing in which the water heater must sit without any draws taking place for at least 12 hours from the end of a recovery from a cold start; (6) specifying the locations of inlet and outlet temperature measurements for storage water heaters, storage-type instantaneous water heaters, and UFHWSTs; and (7) decreasing the time interval for data collection from fifteen minutes to 30 seconds in the thermal efficiency and standby loss tests. While manufacturers cited concerns regarding only the repeatability of the standby loss test in response to comments to the February 2014 RFI, DOE has tentatively concluded that the following proposed modifications would improve the repeatability of both tests. Unless otherwise specified in the following paragraphs, DOE proposes that these changes would apply to thermal efficiency and standby loss tests for all CWH equipment (as applicable).

(1) *Addition of a maximum air draft stipulation, as recommended by HTP.* This modification would allow for more consistent ambient conditions between tests and testing locations, as well as limit the effect of air draft on testing results. DOE proposes to add a requirement that while conducting the thermal efficiency and standby loss tests and during the proposed soak-in period (as applicable), a water heater must be protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement, to be measured within three feet of the jacket of the water heater. This requirement is similar to the requirement adopted for testing consumer water heaters and certain commercial water heaters in the July 2014 final rule. 79 FR 40542, 40569 (July 11, 2014). DOE notes that Annex E.1 of ANSI Z21.10.3–2015 requires that water heater placement in the test room shall be protected from drafts. This modification simply clarifies the meaning of "protected from drafts" by setting a requirement for the maximum allowable draft during the test. DOE proposes that the air draft be measured prior to beginning the soak-in period and thermal efficiency and standby loss tests, and that no actions can be taken during the conduct of the tests or the soak-in period that would increase the air draft near the water heater being tested.

(2) *A decrease in the allowed maximum variance for ambient room temperature for both the thermal efficiency and standby loss tests.* The current test procedure at 10 CFR 431.106 references Exhibits G.1 and G.2 of ANSI Z21.10.3–2011, which require that the ambient room temperature be maintained at 75 °F ± 10 °F, and that the ambient room temperature not vary by more than ±7 °F from the average ambient room temperature during the test. DOE proposes requiring that the ambient room temperature be maintained at 75 °F ± 5 °F and that the room temperature not vary by more than ±2.0 °F from the average ambient room temperature while setting thermostats and verifying steady-state operation, between the first and second cut-outs prior to the standby loss test (as applicable), and during the thermal efficiency and standby loss tests and proposed soak-in period (as applicable) for all CWH equipment.

(3) *Addition of a requirement for measurement of test air temperature for gas-fired and oil-fired commercial water heating equipment.* DOE understands that the entering air temperature can have a significant impact on combustion in gas-fired and oil-fired CWH equipment. To improve repeatability of the thermal efficiency and standby loss tests for these classes of equipment, DOE proposes to require measurement of test air temperature, within 2 feet of the air inlet to the water heater. For CWH equipment that does not have a specific air inlet, DOE proposes that the test air temperature be measured within 2 feet of the jacket of the water heater closest to where air would be drawn for combustion. DOE also proposes a requirement that the test air temperature may not vary by more than ±5 °F from the ambient room temperature at any measurement interval during the course of the thermal efficiency or standby loss tests (as applicable) or while establishing steady-state operation prior to the thermal efficiency test for gas-fired and oil-fired CWH equipment. For units with multiple air inlets, DOE proposes that the test air temperature must be measured at each air inlet, and that the specified tolerance on deviation from the ambient room temperature must be maintained at each air inlet. This required tolerance for test air temperature was modeled after AHRI 1500–2015 in order to remain consistent with common industry practices. However, DOE proposes that this test air temperature requirement not apply to the standby loss test for flow-activated instantaneous water heaters proposed in section III.G of this NOPR, because the burner will not activate during the test. DOE also does not propose a test air temperature requirement for electric water heaters because electric water heaters are not powered by combustion, and, therefore, the test air temperature does not affect the efficiency of the heating elements.

(4) *Establishment of a requirement for ambient relative humidity of 60 percent ±5 percent for gas-fired and oil-fired commercial water heating equipment.* DOE understands that humidity can have a significant effect on the tested efficiency of gas-fired and oil-fired CWH equipment, particularly condensing equipment. High humidity would enable equipment to capture more latent heat from combustion gases, thereby resulting in a higher measured

efficiency. Therefore, the lack of a specification for ambient humidity in DOE's current test procedures for gas-fired and oil-fired CWH equipment can lead to variation in test results between test labs. DOE recognizes that this effect would be noticeable in tests for both thermal efficiency and standby loss. Therefore, DOE proposes to amend its test procedures by specifying a requirement that ambient relative humidity be set and maintained at 60 percent ±5 percent for gas-fired and oil-fired CWH equipment while verifying steady-state operation and during the thermal efficiency and standby loss tests, so as to minimize this effect, which should reduce variability in test results. However, DOE proposes that this ambient humidity requirement not apply to the standby loss test for flow-activated instantaneous water heaters proposed in section III.G of this NOPR, because the burner will not activate during the test. DOE also does not propose an ambient humidity requirement for electric water heaters because electric water heaters are not powered by combustion and, therefore, the ambient air humidity does not affect the efficiency of the heating elements. Also, DOE proposes that the ambient relative humidity be measured and recorded at the same location as the test air temperature, and at 30-second intervals during the entire test. For units with multiple air inlets, DOE proposes that the ambient relative humidity must be measured at each air inlet, and that 60 percent ±5 percent must be maintained at each air inlet. DOE proposes that the ambient relative humidity must remain within the specified range at all times during conduct of the thermal efficiency and standby loss tests.

(5) *Addition of a requirement to perform a pre-test conditioning phase, also known as a soak-in period, for storage water heaters and storage-type instantaneous water heaters.* This proposed provision would require that the water heater remain idle (*i.e.,* no water draws) for at least 12 hours with the thermostats maintained at settings that would achieve the required water temperature (see section III.D for further detail on proposed requirements for setting the tank thermostat), prior to conducting either a thermal efficiency test or standby loss test. This modification is similar to the soak-in period requirement adopted for consumer water heaters and certain commercial water heaters in the July 2014 final rule. 79 FR 40542, 40571 (July 11, 2014). This requirement would help minimize transient heat transfer effects that may reduce the reproducibility of the current standby loss test. However, DOE proposes not to require a soak-in period be conducted prior to beginning an efficiency test (*i.e.,* thermal efficiency or standby loss) if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test. DOE proposes a requirement for a soak-in period for unfired hot water storage tanks with different test conditions in section III.C.

(6) *Specifying the locations for inlet and outlet water temperature measurement for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks.* DOE's current test procedure for CWH equipment incorporates by reference the requirement in Exhibit G.1 of ANSI Z21.10.3–2011 that the inlet and outlet piping be immediately turned vertically downward from the connections on a tank-type water heater to form heat traps and that the thermocouples for measuring inlet and outlet water temperatures be installed before the inlet heat trap piping and after the outlet heat trap piping. While DOE agrees with the general position of the inlet and outlet thermocouples relative to the heat trap piping, the precise location of the thermocouples in terms of distance away from the water heater is not specified. The absence of a clearly defined location for the thermocouples can contribute to variability in the test results. Considering this issue, DOE proposes that the thermocouples be placed with total vertical piping length of 24 inches. For water heaters with vertical connections, the 24 inches of total vertical piping distance is divided into 6 inches of vertical piping upstream from the turn for the heat trap and 18 inches downstream from the turn for the heat trap. For water heaters that have horizontal water connections, DOE proposes that the thermocouples be placed with total horizontal piping length between the thermocouple location and the connection port of six inches. For water heaters that have vertical water connections, due to the differences in the size and dimensions of water heaters, it may not be possible to have the inlet and outlet water piping be turned vertically downward after a fixed horizontal distance of 6 inches away from the connection port. Therefore, for water heaters with vertical connections (opening top or bottom), DOE proposes that the horizontal distance be equal to the distance from the connection port to the edge of the water heater plus 2 inches. Figure III.1, Figure III.2, and Figure III.3 show the three proposed configurations for placement of inlet and outlet water thermocouples for tank-type water heaters. All dimensions shown in the figures and specified in this paragraph are measured from the outer surface of the pipes or water heater jacket (as applicable).

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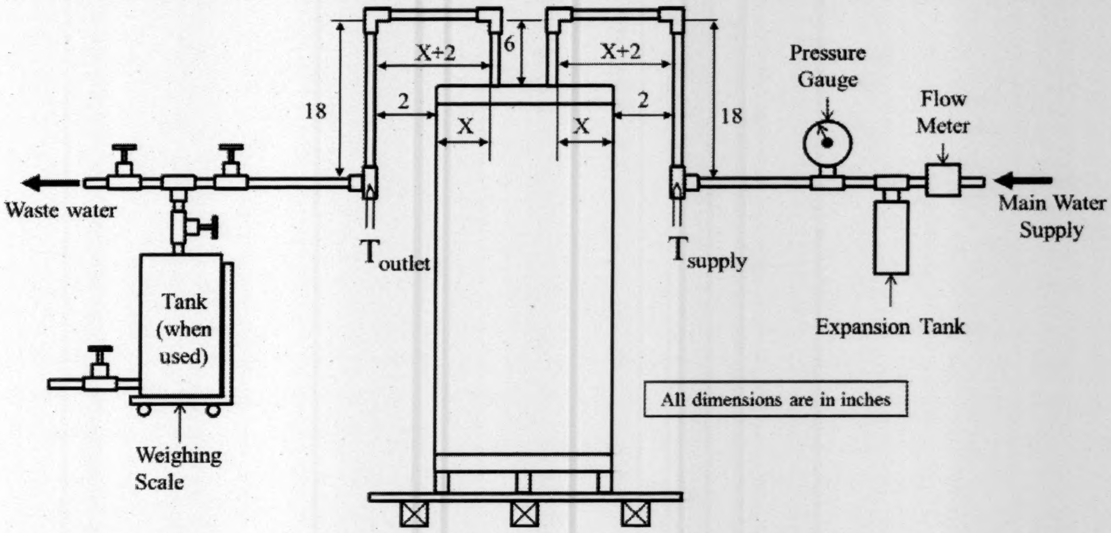
X+2
6
X+2
Pressure Gauge
Flow Meter
18
2
X
X
2
18
Waste water
Main Water Supply
T outlet
T supply
Tank (when used)
Expansion Tank
All dimensions are in inches
Weighing Scale

Figure III.1 Proposed test set-up for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks with vertical (top) connections.

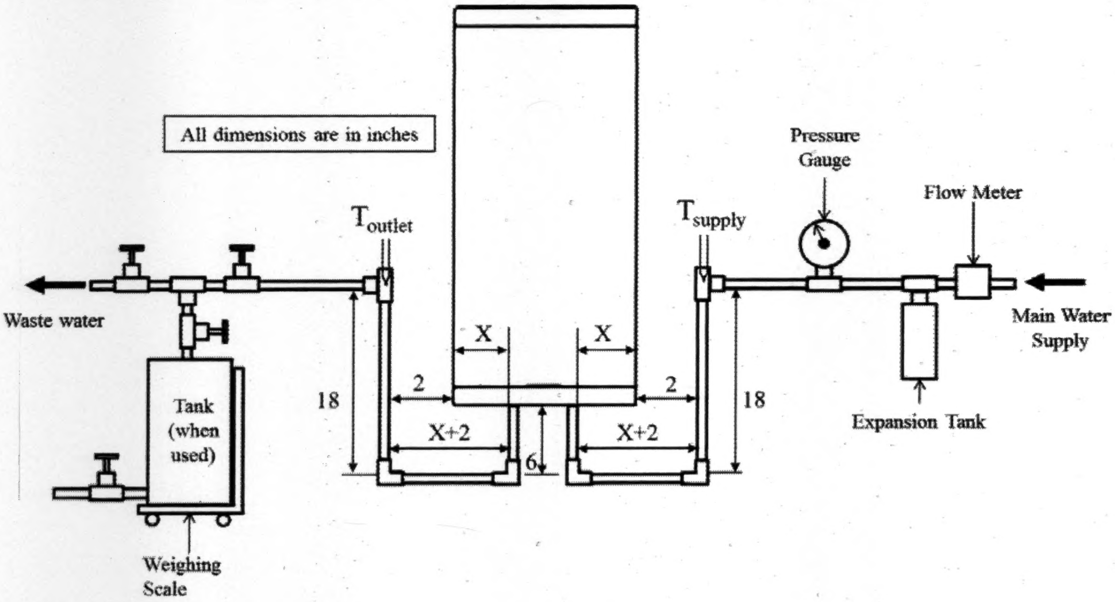
All dimensions are in inches
T_outlet
T_supply
Pressure Gauge
Flow Meter
Waste water
Main Water Supply
X
X
2
2
18
18
X+2
X+2
6
Tank (when used)
Expansion Tank
Weighing Scale

Figure III.2 Proposed test set-up for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks with vertical (bottom) connections.

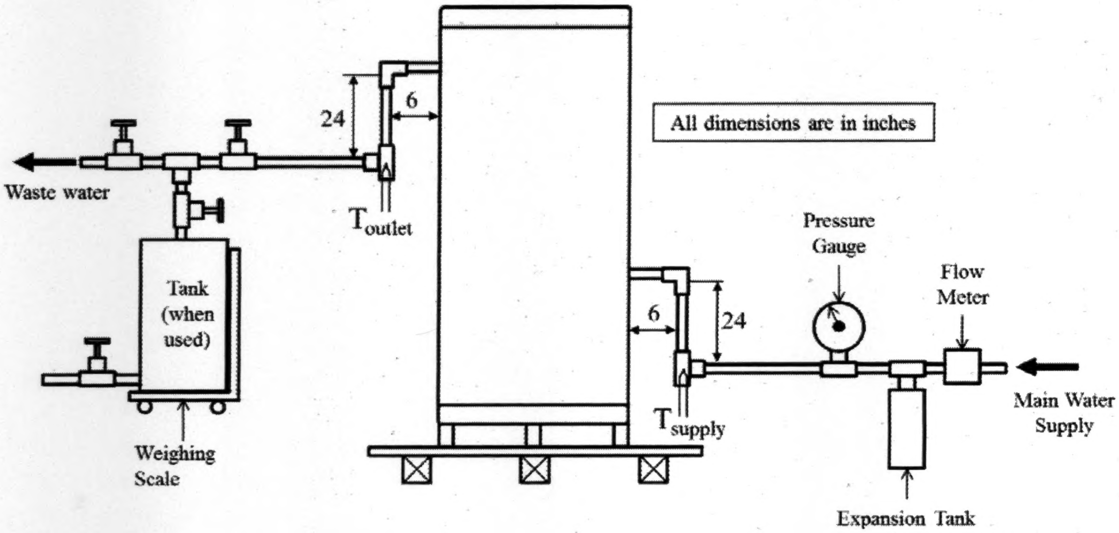
24
6
All dimensions are in inches
Waste water
T_outlet
Tank (when used)
Weighing Scale
Pressure Gauge
Flow Meter
6
24
T_supply
Main Water Supply
Expansion Tank

Figure III.3 Proposed test set-up for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks with horizontal connections.

(7) *Increasing the frequency of data collection.* To further reduce variability in test results, DOE proposes to decrease the length of the time interval between data collection during the thermal efficiency test from 1 minute to 30 seconds and during the standby loss test from 15 minutes to 30 seconds for all CWH equipment (as applicable). This time interval would apply to the measurement of ambient room temperature, test air temperature, and ambient relative humidity for both the thermal efficiency and standby loss tests (as applicable). For the thermal efficiency test, the 30-second time interval would also apply to the measurement of supply and outlet water temperatures. For the standby loss test the 30-second time interval would apply to the measurement of mean tank temperature for storage and storage-type instantaneous water heaters (storage-type instantaneous water heaters are discussed in section III.F), and to measurement of outlet water temperature for instantaneous water heaters and hot water supply boilers. Additionally, DOE proposes that the fuel (*i.e.,* gas or oil) consumption be measured at 10-minute intervals during the thermal efficiency test. These increases in frequency of data collection would increase data granularity, thereby providing more information to identify testing irregularities contributing to test result variance. This modification would also allow for more accurate timing of test start and stop, which may lead to more repeatable results.

DOE also considered three other modifications to improve standby loss test repeatability, but ultimately decided against proposing these modifications for the reasons provided. The three additional considered but rejected modifications include:

(1) *An increase in the number of temperature sensors measuring internal tank temperature from six to twelve.* These sensors would be located at the vertical midpoint of 12 equal volumes of water within the water heater. It was thought that this modification could potentially increase the reliability of the internal tank temperature data and allow better resolution of temperature stratification within the tank. However, based on preliminary test data, DOE observed that increasing the number of sensors had little effect on the outcome of the test and, thus, does not justify the additional burden.

(2) *An increase in the number of thermal probes used to measure ambient temperature from one to at least four.* These probes could be located at the vertical midpoint of the tank at a perpendicular distance of 24 inches (61 cm) from the surface of the jacket, and in each cardinal direction (*i.e.,* North, South, East, and West). It was thought that this modification could potentially help reduce uncertainty of the true ambient temperature profile around the water heater and the associated effect of this uncertainty on the measured standby loss of tested CWH equipment. However, based on preliminary test data, DOE observed that increasing the number of sensors had little effect on the ambient temperature readings, and, thus, little impact on the outcome of the test. Consequently, it would not justify the additional burden.

(3) *Lengthening the required period for establishing steady-state operation prior to the thermal efficiency test to thirty minutes.* DOE's current test procedure references Exhibit G.1 of ANSI Z21.10.3–2011, which requires that the outlet water temperature be established as constant prior to conducting the thermal efficiency test, as determined by no variation in excess of 2 °F over a 3-minute period. For some equipment, a 3-minute period may not be long enough to establish steady-state operation of gas-fired or oil-fired CWH equipment, and a water heater could conceivably exhibit no variation in excess of 2 °F over a 3-minute period before establishing steady-state operation. Additionally, DOE notes that the current test procedure does not impose requirements for maximum variation in inlet water temperature or water flow rate during this period for verifying steady-state operation. Thus, DOE believes that extending the period for determining steady-state operation could improve test method repeatability, and DOE is seeking information and data regarding such a change. DOE notes that for commercial packaged boilers, which are similar equipment to some classes of CWH equipment, AHRI 1500–2015 specifies a 30-minute warm-up period for determining steady-state operation has been achieved.

Issue 3: DOE requests comments and data on its proposed changes to improve the repeatability of the thermal efficiency and standby loss test procedures for certain commercial water heating equipment. Specifically, DOE requests comment on its proposed requirements for ambient relative humidity. DOE does not propose this requirement for testing of electric water heaters, and seeks feedback on whether including such a requirement would improve the repeatability of the standby loss test for electric water heaters. DOE is also seeking comments regarding any additional changes that would improve the repeatability of the thermal efficiency and standby loss tests.

Issue 4: DOE requests comment on the changes to improve test repeatability for its test procedures for certain CWH equipment that were identified but not proposed in this NOPR. If comments suggest that DOE should implement these changes, then DOE will evaluate whether it can adopt those changes in the final rule or must engage in further rulemaking. Particularly, DOE requests data showing what duration for the steady-state verification period would ensure steady-state operation is reached for gas-fired and oil-fired CWH equipment prior to the thermal efficiency test. DOE also seeks data that suggest suitable tolerances for water temperature and flow rate for this steady-state verification period. Additionally, DOE seeks comment on whether different requirements for establishing steady-state operation are warranted for each equipment class of CWH equipment.

C. Test Method for Unfired Hot Water Storage Tanks

EPCA defines an "unfired hot water storage tank" (UFHWST) as a tank used to store water that is heated externally. (42 U.S.C. 6311(12)(C)) The current Federal standard for this equipment type requires a minimum thermal insulation (R-value) of 12.5. 10 CFR 431.110. DOE defines "R-value" as the thermal resistance of insulating material as determined based on ASTM Standard Test Method C177–97 or ASTM Standard Test Method C518–91 and expressed in °F·ft^2·h/Btu. 10 CFR 431.102. In section III.A.3 of this rulemaking, DOE proposes to update references to these standards in its definition for "R-value" by incorporating by reference ASTM C177–13 and ASTM C518–10.

DOE is aware that some manufacturers ship UFHWSTs without insulation, and that uninsulated UFHWSTs may or may not then be insulated on-site. In this rulemaking, DOE makes clear that UFHWSTs shipped without insulation are not compliant with the Federal R-value standard. All UFHWSTs must either be shipped insulated to the R-value standard or shipped together with insulation meeting the R-value standard. Manufacturers of UFHWSTs must certify that the insulation meets the R-value standard prescribed in 10 CFR 431.110, and this certification must be based on testing according to the methods prescribed in the R-value definition. A UFHWST manufacturer may demonstrate compliance with the insulation requirements either by conducting testing itself or by using test data from the insulation material producer. Further, manufacturers of UFHWSTs are responsible for retaining records of the underlying test data used for certification in accordance with current maintenance of records requirements set forth at 10 CFR 429.71.

Because DOE includes ASTM test methods for measuring R-value in its definition of "R-value," DOE does not currently specify a test procedure for measuring energy efficiency of UFHWSTs in 10 CFR 431.106. In the February 2014 RFI, DOE requested comment on whether the R-value is an adequate energy efficiency descriptor for UFHWSTs. DOE also requested comment on the potential for replacing R-value with standby loss, or another metric, as the energy efficiency descriptor for UFHWSTs, and how to establish a standby loss test or other test for this equipment if such a metric is appropriate. 79 FR 10999, 11002 (Feb. 27, 2014).

A.O. Smith, AHRI, and Rheem commented that there is no need for a test procedure to measure the R-value of the insulation on UFHWSTs. (A.O. Smith, No. 7 at pp. 1–2; AHRI, No. 2 at pp. 2–3; Rheem, No. 3 at pp. 1–2) AHRI also commented that the R-value requirement is in no way a measurement of the "efficiency" of an unfired storage tank, and that ASHRAE deliberately did not include a thermal efficiency or standby loss requirement for this equipment in ASHRAE Standard 90.1. (AHRI, No. 2 at pp. 2–3) Bradford White and HTP support the current requirement of a minimum insulation R-value, and Bradford White estimated that replacing the R-value metric with a metric requiring an efficiency test would require 3 days of testing per model. (Bradford White, No. 8 at p. 1; HTP, No. 5 at p. 2) AHRI, HTP, and Rheem also expressed support for the current two ASTM test methods (C177–97 and C518–91) for testing the R-value of insulation for UFHWSTs. (AHRI, No. 2 at pp. 2–3; HTP, No. 5 at p. 2; Rheem, No. 3 at pp. 1–2)

Joint Advocates noted that the two ASTM test methods are intended for flat samples, while UFHWSTs are generally pressure vessels with curved surfaces. (Joint Advocates, No. 4 at p. 2) Joint Advocates recommended replacing the present R-value requirement for UFHWSTs with a standby loss test similar to the test used for electric and fuel-fired commercial water heaters because the current R-value requirement does not ensure that all surfaces of the tank are adequately insulated, nor does it encourage other methods to reduce heat loss, such as anti-siphon connections and/or eliminating thermal bridges. Joint Advocates also recommended that for any units with legitimate needs for field insulation of UFWHSTs, DOE could either allow for a waiver or establish a separate class of uninsulated UFHWSTs. (Joint Advocates, No. 4 at p. 2)

A.O. Smith and AHRI also pointed out that there exists a group of UFHWSTs that are larger than standard volume models and are often built to order. (A.O. Smith, No. 7 at p. 2; AHRI, No. 2 at pp. 2–3) A.O. Smith and AHRI stated that these units are often shipped without insulation and subsequently field-insulated due to shipping and installation considerations that make it impractical to insulate at the site of manufacture. (A.O. Smith, No. 7 at p. 2; AHRI No. 2 at pp. 2–3)

After considering these comments, DOE has tentatively determined that a measurement of energy efficiency of UFHWSTs is necessary to more fully comply with the requirements of 42 U.S.C. 6314(a)(2)–(3), and proposes a standby loss metric and test method to replace the current R-value requirement. Although DOE recognizes that requiring use of a standby loss test will increase test burden for manufacturers, DOE has tentatively concluded that the benefits of such a metric would outweigh this additional burden. Primarily, DOE agrees with Joint Advocates that a standby loss metric would encourage and credit energy-saving technologies that are not measured by the R-value of the insulation and ensure that all surfaces are adequately insulated. As a result, DOE proposes to establish a standby loss test method for UFHWSTs that monitors the decrease in tank temperature from a set temperature. In addition, DOE proposes to amend the definition of "standby loss" at 10 CFR 431.102 to include unfired hot water storage tanks.

Regarding the points from AHRI, A.O. Smith, and Joint Advocates about UFHWSTs that are shipped without insulation and subsequently field-insulated, DOE reiterates that all UFHWSTs must have a minimum thermal insulation R-value of 12.5 when they are shipped from the manufacturer. Any units shipped without a minimum thermal insulation of R–12.5 and then insulated on-site would not be compliant with DOE's current regulations.

To determine the standby loss of an UFHWST, the storage capacity of the tank must first be determined. Section 5.27 of ANSI Z21.10.3–2015 includes a method for measuring the storage capacity, and it states that this method is applicable to water heaters including storage vessels. DOE examined this method and found no reason why it would be inapplicable to UFHWSTs. Therefore, DOE proposes to use the test method described in section 5.27 of ANSI Z21.10.3–2015 to measure the storage capacity of UFHWSTs. DOE includes a procedure for determining storage volume in its proposed test procedure for UFHWSTs that has only clarifying differences from the method presented in section 5.27 of ANSI Z21.10.3–2015. DOE's proposed procedure for determining storage volume is discussed in further detail in section III.G.

Next, DOE considered three possible test methods to determine the standby loss coefficient and hourly standby losses of an UFHWST. The first method considered—and the one that DOE proposes as the test method for UFHWSTs—is based on a method for assessing the energy efficiency of indirect water heaters, which was originally developed by the GAMA,[10] and set forth in Testing Standard IWH–TS–1, "Method to Determine Performance of Indirect-Fired Water Heaters" (March 2003 edition).[11] Under this procedure, the tank is set up as would normally be done in the field, with potable water inlet and outlet piping and supply and return piping connected to an external heat source. This procedure specifies bringing the water in the tank to a mean temperature of 140 °F by the external heat source, and then monitoring the stored water temperature while the heat source is inactive and the water temperature inside the tank decreases. A linear fit is applied to temperature data as the mean tank temperature drops from 137 °F to 133 °F to yield a temperature decay term with units of °F/h. DOE proposes to use this test method as the basis of a test method to determine the standby loss of UFHWSTs but with several modifications. DOE has tentatively concluded that the use of Testing Standard IWH–TS–1 would sufficiently capture the heat loss of UFHWSTs and reduce burden to manufacturers relative to alternative methods, because it is already an industry-accepted procedure that is used in AHRI's certification program for indirect water heaters.

As noted in this preamble, DOE proposes several modifications to Testing Standard IWH–TS–1 to be included in DOE's proposed test procedure for standby loss of UFHWSTs. First, because the nominal tank temperature for determining standby loss for commercial storage water heaters is 140 °F, DOE proposes to calculate standby loss of UFHWSTs using temperature data collected as the mean tank temperature drops from 142 °F to 138 °F instead of 137 °F to 133 °F. To do so, DOE proposes that the tank be filled with water that is heated sufficiently to achieve a mean tank temperature of 145 °F and then be allowed to decrease from that point. Consequently, DOE also proposes to update the water density and specific heat capacity constants used in calculation of standby loss to 8.205 lb/gallon and 0.999 Btu/°F·lb respectively, to correspond to the mid-point of DOE's proposed temperature range (140 °F), instead of the mid-point of the temperature range specified in Testing Standard IWH–TS–1 (135 °F). However, DOE notes that the value for specific heat capacity of water does not change as the temperature increases from 135 °F to 140 °F, with the number of significant figures specified in Testing Standard IWH–TS–1.

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[10] The Air-Conditioning and Refrigeration Institute (ARI) and GAMA merged to become AHRI on January 1, 2008.

[11] Available at: *http://www.org/App_Content/ahri/files/standards%20pdfs/Indirect-Fired%20Water%20Heater%20Testing%20Standard03.pdf* (last accessed February 12, 2015).

DOE also proposes to adopt the same ambient room temperature requirement for all CWH equipment that is discussed in section III.B. Specifically, DOE proposes that the ambient room temperature must be maintained at 75 °F ± 5 °F during the test (as measured at each 30-second interval), and the measured room temperature must not vary by more than ±2.0 °F from the average ambient room temperature during the test. While Testing Standard IWH–TS–1 specifies an ambient room temperature of 70 °F, DOE notes that many manufacturers of UFHWSTs also manufacture storage water heaters. Therefore, DOE expects that manufacturer burden would be reduced if storage water heaters and UFHWSTs can be tested in the same test room, and DOE's proposal is consistent with that objective. Additionally, DOE proposes a requirement for maximum air draft in section III.B that applies to the soak-in period and standby loss test for UFHWSTs. Similar to ambient room temperature, DOE expects that aligning this requirement with that for other classes of CWH equipment will reduce testing burden for CWH manufacturers. DOE also proposes a requirement for a soak-in period to be conducted prior to beginning the standby loss test for UFHWSTs. In this soak-in period, the tank must sit without any draws taking place for at least 12 hours after being filled with water such that a mean tank temperature of 145 °F ± 5 °F is achieved. After completion of the soak-in period, DOE would require that the UFHWST be filled again such that a mean tank temperature of 145 °F ± 5 °F is achieved, because the stored water temperature would decrease during the soak-in period. Additionally, DOE proposes requirements for piping insulation and water supply similar to those for other classes of CWH equipment included in Annex E.1 of ANSI Z21.10.3–2015.

DOE also proposes to collect temperature data at intervals of 30 seconds during this test, as opposed to the 15-minute intervals specified by the IWH–TS–1 test method. DOE has determined that a higher number of data points will improve the accuracy of the least-squares regression and that, given the data storage capacity of modern data acquisition equipment, the higher frequency of data collection will pose only a negligible additional burden upon laboratories, as compared to the current 15-minute data collection interval. DOE also proposes to convert the decay rate metric to the standby loss metric currently applied to commercial storage water heaters, which has units of Btu/h.

DOE also considered two other approaches to determine the standby loss for UFHWSTs and is presenting these alternatives as part of this NOPR for comment on their merits compared to the proposed method. The first alternative is similar to the method proposed, but uses a different condition to end the standby loss test. Specifically, under this approach, the test would end 24 hours after the beginning of the test, instead of after the mean tank temperature reaches a specified temperature. However, the use of such a test ending condition would result in different final water temperatures for units with different rates of heat loss. This variation in final water temperature would impart an undesirable benefit to UFHWSTs that lose heat more quickly, because the rate of heat transfer from water to the surrounding air decreases as the corresponding temperature difference decreases. Additionally, DOE believes that a change in test ending condition to a 24-hour time limit may result in unnecessary test burden for manufacturers, as it would likely extend the duration of the test. In light of the potential downsides to this alternative, DOE has tentatively concluded that the test method proposed in this document (based on the industry-accepted IWH–TS–1 test method) would sufficiently capture the rate of heat loss from the tank while potentially allowing for a shorter test time.

DOE also considered a second alternative test method that would maintain the set point of the hot water within the UFHWST, by connecting an UFHWST to an external heat source (*i.e.*, a water heater or boiler) that would replace water in the tank that has cooled down with water that has been heated by the external source. Circulation from the external heat source to the water heater would be controlled based on the internal tank temperature. The amount of water circulated into the UFHWST from the external source and the temperature of supply water and return water would be monitored during reheat cycles to determine the amount of energy supplied to the tank. This test would start one hour after a reheat cycle and would progress until one hour after completion of the first reheat cycle after 24 hours have elapsed since the start of the test. Calculation of standby loss would include the change in stored energy within the UFHWST, as well as energy supplied to the UFHWST by the external heat source. While this test method would more closely align with DOE's standby loss test procedures for electric and fuel-fired CWH equipment and be more representative of field use of UFHWSTs, DOE has tentatively concluded that this method would be overly burdensome to manufacturers and could lead to increased variability in test results. Use of other CWH equipment to heat water being supplied to the UFHWST could lead to variability based on variation in the equipment and piping used for testing. Based on preliminary test data, DOE observed similar results for a method that uses circulation with an external heat source and a method that does not; therefore, DOE has tentatively concluded that a method using circulation with an external heat source would not provide a more accurate result that would be commensurate with the additional testing burden of such an approach.

Issue 5: DOE requests comment on the proposed test procedure to determine the standby loss for UFHWSTs, and on whether any other methods, including those detailed in this NOPR, would lead to a better test. Specifically, DOE solicits feedback on whether the proposed test would be long enough to determine an accurate standby loss rating, whether the use of a linear approximation of the temperature decay is sufficient to estimate the standby loss, whether running the test by simply letting the temperature decay (rather than providing external heat to bring the temperature of the water back to operational temperature) is appropriate, and whether the adoption of test conditions (*i.e.*, ambient room temperature, maximum air draft, water temperature) similar to that of other classes of CWH equipment is appropriate. DOE also seeks comment on whether any of its identified alternatives could be modified to improve their repeatability and to decrease test burden, thereby supporting further consideration.

D. Procedure for Setting the Tank Thermostat for Storage and Storage-Type Instantaneous Water Heaters

DOE's test method for measuring the energy efficiency of CWH equipment currently requires that the thermostat be set to achieve specific conditions for the mean tank temperature before the test may begin. In particular, section g of Exhibit G.1 of ANSI Z21.10.3–2011 (which is currently incorporated by reference into the DOE test procedure) requires that before starting testing, the thermostat setting must be adjusted such that, when starting with the water in the system at 70 °F ± 2 °F, the maximum mean tank temperature will be 140 °F ± 5 °F after the thermostat reduces the gas supply to a minimum. DOE understands that some units may have difficulty achieving the required mean tank temperature condition, and in the February 2014 RFI DOE requested feedback on potential test procedure amendments to address this issue. 79 FR 10999, 11003 (Feb. 27, 2014).

In response to the February 2014 RFI, the four manufacturers among the interested parties (A.O. Smith, Bradford White, HTP, and Rheem), as well as AHRI, expressed support for changing the set point conditions to require monitoring the outlet water temperature rather than the mean tank temperature. (Bradford White, No. 8 at p. 1; Rheem, No. 3 at p. 2; HTP, No. 5 at p. 2; A.O. Smith, No. 7 at p. 2; AHRI, No. 2 at p. 4) A.O. Smith, Rheem, and AHRI expressed support for maintaining the set point condition at 140 °F ± 5 °F for the outlet water temperature. (A.O. Smith, No. 7 at p. 2; Rheem, No. 3 at p. 2; AHRI, No. 2 at p. 4) A.O. Smith stated that certain designs of CWH equipment cannot reach a mean tank temperature of 140 °F ± 5 °F, including down-fired, condensing equipment with reduced firing rates, and solar or other renewable source equipment. (A.O. Smith, No. 7 at p. 2) DOE received no comments opposing a potential change from setting the thermostat based on the mean tank temperature to setting the thermostat based on the temperature of the delivered water.

After carefully considering these comments, DOE proposes to modify the thermal efficiency and standby loss test procedures for gas-fired and oil-fired storage water heaters and storage-type instantaneous water heaters to require that before starting testing, the thermostat setting be adjusted such that, when starting with the water in the system at 70 °F ± 2 °F, the maximum outlet water temperature will be 140 °F ± 5 °F after the thermostat reduces the gas supply to a minimum. DOE has tentatively concluded that changing from a mean tank temperature requirement to an outlet temperature requirement would better accommodate designs of gas-fired and oil-fired water heaters that are not designed to have high mean tank temperatures (*e.g.*, condensing water heaters) or that rely upon stratification.

DOE does not propose changing the mean tank temperature requirement to an outlet water temperature requirement for electric storage water heaters because of complications with setting tank thermostats. Electric storage water heaters have multiple heating elements and a thermostat corresponding to each element, and each thermostat needs to be set prior to beginning the standby loss test. Therefore, DOE reasons that electric storage water heaters, which vary in configuration and number of heating elements, are not well-suited to an outlet water temperature requirement because it is unclear how the lower thermostats would be set to achieve a designated outlet water temperature. A consistent, reproducible process for setting the thermostats is essential to having a repeatable test. Therefore, DOE proposes to maintain a mean tank temperature requirement for the standby loss test for electric storage water heaters. However, DOE proposes to clarify its language specifying the method for setting thermostats in an electric storage water heater with multiple thermostats. Specifically, DOE proposes to clarify that the thermostats are to be set in immediate succession, starting from the topmost thermostat. DOE also proposes to clarify that when setting each thermostat, the mean tank temperature is calculated using only temperature readings measured at locations higher in the tank than the heating element corresponding to the thermostat being set, with the exception of the bottommost thermostat. Finally, DOE proposes to clarify that all thermostats below the thermostat being tested must be turned off so that no elements below the thermostat being tested are in operation.

Issue 6: DOE seeks comment on its proposed change to its requirements for setting the tank thermostat in the thermal efficiency and standby loss test procedures for gas-fired and oil-fired storage and storage-type instantaneous water heaters from measurement of mean tank temperature to measurement of outlet water temperature.

Issue 7: DOE seeks comment on its tentative decision to maintain a mean tank temperature requirement for the standby loss test for electric storage water heaters. DOE also requests comment on its clarifying language for setting tank thermostats for electric storage water heaters with multiple thermostats.

E. Clarifications to the Thermal Efficiency and Standby Loss Test Procedures

The calculation of thermal efficiency included in the current DOE test procedure for gas-fired and oil-fired CWH equipment at 10 CFR 431.106 (which incorporates the method used in Exhibit G.1 of ANSI Z21.10.3–2011) does not consider change in internal stored energy of the stored water.[12] In the February 2014 RFI, DOE sought public comment on whether it is necessary to account for the potential variation in stored thermal energy inside the water heater during the course of the test, and specifically whether there is a need to account for losses in the internal stored energy in the thermal efficiency calculation. 79 FR 10999, 11003 (Feb. 27, 2014). In addition, DOE sought feedback on whether there is need for clarification to ensure that the water flow rate is adjusted so that the burner is fired at a constant firing rate or whether cycling of the burner is allowed. *Id.*

In response, DOE received several comments from interested parties and stakeholders. AHRI commented that no change is required to the test procedure to address this issue. According to AHRI, the intent of the test method is that the burner be operated at a continuous, full-input firing rate, and once steady state is achieved, there would not be any issue with regards to potential changes in stored heat within the water heater. (AHRI, No. 2 at p. 4) Rheem deferred to AHRI's comments of not requiring any change in the thermal efficiency test method. (Rheem, No. 3 at p. 2) Bradford White, HTP, and A.O.

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[12] The thermal efficiency test procedure in Exhibit G.1. of ANSI Z21.10.3–2011 is a steady-state procedure where the supply water temperature is maintained at 70 °F ± 2 °F, outlet water temperature is maintained at 70 °F ± 2 °F above the supply water temperature, and the flow rate is adjusted to a constant value that can maintain these temperatures throughout the duration of the test. Because the supply and outlet water temperatures and the water flow rate are not varied while taking the measurements to calculate the thermal efficiency, rate of change of stored energy in the water heater would be zero.

Smith also commented on this issue. Bradford White did not see any merit in modifying the test procedure to account for variation in thermal energy stored in the tank. As a possible clarification, Bradford White suggested adding a sentence stating that, "flow rate must achieve continuous full rate burner operation at the required stable outlet water temperature." According to Bradford White, stored energy would only be a significant consideration if the test conditions are not allowed to stabilize sufficiently or if the conditions are not controlled tightly. Bradford White recommended additional investigation of any modification that is proposed if DOE decides to amend the test procedure to account for stored energy changes. (Bradford White, No. 8 at pp. 1–2) A.O. Smith commented that the current test procedure for determining thermal efficiency has been used for a very long time without any confusion, and accordingly, A.O. Smith did not recommend any changes in the current test procedure. (A.O. Smith, No. 7 at p. 2) HTP commented that units are commonly pre-conditioned before the test, and recommended requiring products be pre-conditioned as part of the DOE test method. Further, HTP asserted that if tanks are pre-conditioned, it would not expect any additional accuracy achieved by accounting for the difference in energy maintained within the storage tank during the test. (HTP, No. 5 at p. 3) Joint Advocates encouraged any changes that would minimize systematic errors if the current test procedure is insufficiently specific and if an agreement can be reached on a reasonable method whose cost is commensurate to the value of the change. (Joint Advocates, No. 4 at p. 2)

DOE considered all comments received from interested parties in response to this issue. Based on the comments received, DOE has tentatively decided not to implement any changes in the current thermal efficiency test methods or calculations for CWH equipment to account for changes in thermal energy stored in the water heater during the course of the 30-minute test. However, DOE proposes to clarify the requirements for maintaining steady-state operation throughout the thermal efficiency test. Specifically, DOE proposes to clarify that no settings on the water heater may be changed during the course of the thermal efficiency test, once steady-state operation is achieved, as determined by no variation of outlet water temperature in excess of 2 °F over a 3-minute period. This includes setting the flow rate during testing such that the heater operates at full firing rate (*i.e.,* no modulation or cut-outs) for the entire duration of the test. Although the current test method is clear in requiring the test conditions to reach steady state prior to starting the test, there could be some confusion on whether these conditions are required to be maintained for the entire duration of the test. DOE proposes to add a statement to clarify steady-state operation during the thermal efficiency test. The proposed clarifying statement specifies that the test entity must maintain the outlet water temperature at 70 °F ± 2 °F above the supply water temperature and ensure the burner fires continuously at the full firing rate (*i.e.,* no modulation or cut-outs) for the entire duration of the thermal efficiency test. Further, the proposed statement clarifies that once steady-state operation is achieved, as determined by no variation of the outlet water temperature in excess of 2 °F over a 3-minute period, no settings on the water heating equipment may be changed until measurements for the thermal efficiency test are finished.

Additionally, DOE proposes to clarify a similar requirement for the standby loss test for CWH equipment other than those meeting DOE's proposed definition for "flow-activated instantaneous water heater." DOE proposes to require that after the first cut-out before beginning the standby loss test, no settings may be changed on the water heating equipment until measurements for the standby loss test are finished.

Issue 8: DOE requests comment on its proposed clarifying statements regarding steady-state operation and manipulation of CWH equipment settings during efficiency tests.

F. Definitions for Certain Consumer Water Heaters and Commercial Water Heating Equipment

1. Consumer Water Heaters

EPCA's definition of water heater specifies input ratings at or below which water heaters are to be classified as consumer water heaters (*e.g.,* 75,000 Btu/h for gas-fired storage water heaters; 12 kW for electric storage water heaters and electric instantaneous water heaters; 210,000 Btu/h for oil-fired instantaneous water heaters). (42 U.S.C. 6291(27)) DOE's regulatory definition of "water heater" restates the definition from the consumer products part of EPCA. (42 U.S.C. 6291(27); 10 CFR 430.2) In addition to adopting EPCA's definition of water heater, DOE had defined a variety of terms that helped specify the test procedure provisions that applied to specific kinds of water heaters. See, *e.g.,* 10 CFR part 430, subpart B, appendix E, in the 10 CFR parts 200 to 499 edition, revised as of January 1, 2015 (defining, for example, gas instantaneous water heater and electric storage-type water heater). These test procedure definitions included provisions related to water temperature design characteristics and rated storage volume. The standards at 10 CFR 430.32 and the water heater definition at 10 CFR 430.2 did not include any such limitations.

In the July 11, 2014 test procedure final rule, in an effort to consolidate all relevant definitions in 10 CFR 430.2, DOE removed the definitions for specific kinds of consumer water heaters from its test method at appendix E to subpart B of part 430 and added definitions to 10 CFR 430.2 (*i.e.,* "Electric heat pump water heater," "Electric instantaneous water heater," "Electric storage water heater," "Gas-fired heat pump water heater," "Gas-fired instantaneous water heater," "Gas-fired storage water heater," "Oil-fired instantaneous water heater," and "Oil-fired storage water heater"). 79 FR 40542, 40549, 40566–67 (July 11, 2014). These definitions became effective on July 13, 2015, and excluded products with a rated storage capacity greater than 120 gallons and in some cases included limitations with respect to units designed to heat and store water at a thermostatically controlled temperature less than or equal to 180 °F. 79 FR 40542, 40566–67 (July 11, 2014). These changes to the definitions were proposed and finalized after the publication of the April 16, 2010 final rule setting amended standards for consumer water heaters, and they were not effective until after the April 16, 2015 compliance date for those standards. As noted previously, the standards and definition set forth in EPCA do not include any requirement related to the water temperature or storage capacity. Therefore, prior to the effectiveness of July 2014 regulation, any product meeting the definition of a "water heater" would have been subject to the statutory standards applicable to consumer water heaters, regardless of the water delivery temperature or storage capacity.

DOE now proposes to correct the definitions for specific types of consumer water heaters included at 10 CFR 430.2 by removing from the definitions the specifications related to the water temperature and storage capacity. Thus, a model that would otherwise meet the definition of a consumer water heater does not "become" commercial as the result of the unit's capability of producing water at temperatures above 180 °F. More generally, a product that utilizes gas, oil, or electricity to heat potable water for use outside the heater upon demand that does not meet the statutory definition of "water heater" at 42 U.S.C. 6291(27) as implemented by this proposed rule, if adopted, would be a commercial water heater, subject to the standards for such water heaters as set forth in 42 U.S.C. 6313.

Furthermore, DOE notes that, if a manufacturer offers a product that meets the definition of a water heater at 10 CFR 430.2, but cannot be tested by the applicable test procedure, the manufacturer should notify DOE and request a waiver from the applicable test method using the procedures at 10 CFR 430.27. If a waiver were granted, DOE would update its test procedure in the next rulemaking for consumer water heaters. DOE does not anticipate, however, that such a waiver would be needed. The UEF test procedure was developed quite recently and was designed to span the consumer product/commercial equipment boundary; accordingly, DOE expects that all units (irrespective of designed water temperature and/or rated storage capacity) can be tested without difficulty.

In its definitions at 10 CFR 430.2, DOE currently defines the terms "electric heat pump water heater" and "gas-fired heat pump water heater." In its energy conservation standards for consumer water heaters at 10 CFR 430.32(d), DOE does not use the terms "electric heat pump water heater" or "gas-fired heat pump water heater." DOE's Uniform Test Method for Measuring the Energy Consumption of Water Heaters at appendix E to subpart B of part 430 also does not use these terms. Therefore, DOE proposes to remove these terms.

As discussed in the previous paragraphs, DOE proposes to revise the definitions for "Electric instantaneous water heater", "Electric storage water heater", "Gas-fired instantaneous water heater", "Gas-fired storage water heater", "Oil-fired instantaneous water heater", "Oil-fired storage water heater", in its regulations of consumer water heaters at 10 CFR 430.2 as set out in the regulatory text at the end of this document.

Issue 9: DOE requests comment on its proposal to amend the definitions for consumer water heaters codified at 10 CFR 430.2 by removing the water temperature and storage capacity provisions. DOE also requests comment on its proposal to remove the definitions at 10 CFR 430.2 for "electric heat pump water heater" and "gas-fired heat pump water heater."

2. Commercial Water Heating Equipment

DOE currently includes several definitions that include the terms "rated input" or "input rating" in its regulations for CWH equipment at 10 CFR 431.102. These definitions include "hot water supply boiler," "instantaneous water heater," "residential-duty commercial water heater," and "storage water heater." In section III.K of this NOPR, DOE proposes a new definition for "fuel input rate," a value to be determined for all gas-fired and oil-fired CWH equipment. Therefore, DOE proposes to replace the terms "rated input" and "input rating" with the term "fuel input rate" for gas-fired and oil-fired CWH equipment in the definitions for CWH equipment at 10 CFR 431.102.

DOE's current definitions for "storage water heater" and "instantaneous water heater" in its regulations for CWH equipment codified at 10 CFR 431.102 do not include any criteria that exclude units that meet DOE's current definitions for consumer water heaters, as codified at 10 CFR 430.2. Therefore, DOE proposes to clarify these definitions for commercial water heaters by adding the input capacity criteria that distinguish between consumer and commercial water heaters for each energy source, as specified in EPCA's definition for consumer water heater. (42 U.S.C. 6291(27)) These proposed changes are consistent with DOE's proposed changes to its definitions for consumer water heaters, as discussed in section III.F.1.

DOE currently includes the definition for "instantaneous water heater" in its regulations for CWH equipment at 10 CFR 431.102. An instantaneous water heater is a water heater that has an input rating not less than 4,000 Btu/hr per gallon of stored water, and that is industrial equipment, including products meeting this description that are designed to heat water to temperatures of 180 °F or higher.

DOE believes that the last clause of the definition for "instantaneous water heater," which includes units capable of heating water to temperature at or above 180 °F, does not serve a purpose in the definition. Without this clause, it would be assumed that units with this capability would be included in the definition because there is no restriction indicating otherwise. Therefore to simplify the definition, DOE proposes to remove this clause from the definition for "instantaneous water heater." Additionally, with DOE's proposed addition of input criteria that distinguish between consumer and commercial water heaters previously discussed in this section, DOE believes that the clause "that is industrial equipment" does not serve to further clarify the scope of units covered by this definition. Therefore, DOE proposes to remove this clause from its definitions for "instantaneous water heater" and "storage water heater," and revises the definitions as set out in the regulatory text at the end of this document.

In its regulations for CWH equipment at 10 CFR 431.102, DOE currently includes a definition for "packaged boiler" that is identical to that included for "commercial packaged boiler" at 10 CFR 431.82. DOE includes this definition for "packaged boiler" at 10 CFR 431.102 because the regulations for CWH equipment also include a definition for "hot water supply boiler," and this definition specifies that a hot water supply boiler is a kind of packaged boiler. To simplify its regulations and reduce repetition, DOE proposes to remove the definition for "packaged boiler" from its regulations for CWH equipment at 10 CFR 431.102. Consequently, in its definition for "hot water supply boiler," DOE proposes to replace the term "packaged boiler" with the term "packaged boiler (as defined in § 431.82)."

Issue 10: DOE requests comment on its proposed changes to its definitions for CWH equipment: (1) Replacing the terms "rated input" and "input rating" with "fuel input rate" for gas-fired and oil-fired CWH equipment to match DOE's proposed definition for "fuel input rate;" (2) modifying DOE's definitions for "instantaneous water heater" and "storage water heater" by adding the input criteria that separate consumer water heaters and commercial water heaters and removing several phrases that do not serve to clarify coverage of units under the definitions; and (3) removing the definition of "packaged boiler."

In section III.G, DOE discusses the reasons for a separate test procedure for water heaters and hot water supply boilers that require flow of water for heating water, and proposes a definition for "flow-activated water heater," along with a test procedure for flow-activated water heaters as set out in the regulatory text at the end of this document.

In section III.J, DOE proposes a definition for "commercial heat pump water heater," as well as a test procedure for commercial heat pump water heaters as set out in the regulatory text at the end of this document.

3. Residential-Duty Commercial Water Heaters

As required by AEMTCA, DOE established a uniform efficiency descriptor and accompanying test method for consumer water heaters and certain commercial water heaters in the July 2014 final rule. 79 FR 40542 (July 11, 2014). Specifically, AEMTCA required that the uniform efficiency descriptor and test method apply to all covered water heaters, including both consumer or commercial water heaters, except for certain commercial water heaters that do not have a residential use, can be clearly described, and are effectively rated using the thermal efficiency and standby loss descriptors. (42 U.S.C. 6295(e)(5)(F)) In the July 2014 final rule, DOE established input and volume criteria to distinguish commercial water heaters that do not have residential applications, based on comments from stakeholders. 79 FR 40542, 40586 (July 11, 2014). However, for four classes of residential-duty commercial water heaters—electric storage water heaters, heat pump water heaters, gas-fired instantaneous water heaters, and oil-fired instantaneous water heaters—the input criteria established to separate residential-duty commercial water heaters and commercial water heaters are identical to those codified at 10 CFR 430.2 that separate consumer water heaters and commercial water heaters. The criteria for these classes are shown in Table III–1. Because these input criteria are identical, by definition, no models can be classified under these four residential-duty equipment classes. Therefore, to eliminate potential confusion, DOE proposes to remove these classes from the definition for "residential-duty commercial water heater" codified at 10 CFR 431.102.

TABLE III–1—INDICATOR OF NON-RESIDENTIAL APPLICATION FOR CERTAIN CLASSES OF CWH EQUIPMENT

Water heater class	Indicator of non-residential application
Electric storage	Rated input >12 kW; Rated storage volume >120 gallons.
Heat pump with storage	Rated input >12 kW; Rated current >24A at a rated voltage of not greater than 250 V; Rated storage volume >120 gallons.
Gas-fired instantaneous	Rated input >200 kBtu/h; Rated storage volume >2 gallons.
Oil-fired instantaneous	Rated input >210 kBtu/h; Rated storage volume >2 gallons.

DOE proposes to revise the definition for "residential-duty commercial water heater" as set out in the regulatory text at the end of this document.

Issue 11: DOE requests comment on its proposal to modify the definition of "residential-duty commercial water heater" by removing from its scope the following classes: Electric storage water heaters, heat pump water heaters with storage, gas-fired instantaneous water heaters, and oil-fired instantaneous water heaters.

4. Storage-Type Instantaneous Water Heaters

The definitions for "instantaneous water heater" and "hot water supply boiler" set forth in 10 CFR 431.102 include CWH equipment with an input rating of at least 4,000 Btu/h per gallon of stored water. These definitions, therefore, include both instantaneous water heaters and hot water supply boilers without integral storage tanks, as well as instantaneous water heaters with integral storage tanks (but with at least 4,000 Btu/h of input per gallon of stored water). DOE believes these two groups of equipment—water heaters with and without integral storage tanks—are fundamentally different in their construction and application and have different energy losses that need to be accounted for during efficiency testing. DOE has tentatively concluded that instantaneous water heaters with an integral storage tank ("storage-type instantaneous water heaters") should be tested in a manner similar to commercial storage water heaters. Therefore, DOE proposes to adopt a test method specifically applicable to "storage-type instantaneous water heaters" that is the same as the test method for commercial storage water heaters. DOE proposes to define "storage-type instantaneous water heater" as set out in the regulatory text at the end of this document.

Issue 12: DOE seeks comment on its proposed definition of "storage-type instantaneous water heater."

It is DOE's understanding that storage-type instantaneous water heaters are very similar to storage water heaters, but with a higher ratio of input rating to tank volume. This higher input-volume ratio is achieved with a relatively larger heat exchanger paired with a relatively smaller storage tank. However, through a review of product literature, DOE noted no significant design differences between models in these two proposed equipment classes that warrant separate test procedures for thermal efficiency or standby loss. Therefore, DOE proposes that the proposed test procedures for storage water heaters apply also to storage-type instantaneous water heaters.

G. Standby Loss Test for Flow-Activated Instantaneous Water Heaters

The current Federal standby loss test method for CWH equipment incorporates by reference ANSI Z21.10.3–2011, including Exhibit G.2 which assumes that the water heater would automatically initiate the next firing cycle when the internal water temperature (measured using the internal tank thermostat) falls below its allowable minimum value. An underlying assumption for the standby loss test is that the ignition of the burner or activation of the electric element is solely dependent on the feedback control signal from the internal tank thermostat. This assumption, although true for most CWH equipment, is not applicable to certain instantaneous water heaters and hot water supply boilers that require continuous water flow through the heat exchanger in order to activate the next firing cycle.

Measuring standby loss for such flow-activated instantaneous water heaters with a storage volume greater than or equal to 10 gallons was raised as an issue by AHRI. (AHRI, No. 2 at pp. 4–5) Specifically, AHRI commented that the current standby loss test is designed for tank-type water heaters and does not address water heaters that can fire only when hot water is being drawn. (AHRI, No. 2 at pp. 4–5) On August 25, 2014, AHRI provided a supplemental comment with a recommended standby loss test method for tube-type instantaneous water heaters having a capacity of 10 gallons or more ("2014 AHRI-recommended test method"), which includes a suggested test method for models that are flow-activated. AHRI also mentioned in its comments that their recommended test method is being considered as an addition to the ANSI Z21.10.3 standard, and was at that time under review by the ANSI Z21/83 committee. (AHRI, No. 10 at p. 1)

DOE considered the comments received from AHRI and reviewed its recommended standby loss test method for tube-type instantaneous water heaters having a capacity of 10 gallons or more. Based on its review, DOE agrees with AHRI's argument that the current standby loss test method as set forth in Exhibit G.2 of ANSI Z21.10.3–2011 (incorporated by reference in the DOE test procedures) is designed for thermostatically-controlled, tank-type (or storage) water heaters and acknowledges concerns about the applicability to flow-activated water heaters. The current test procedure does not provide any indication of how to test flow-activated instantaneous water heaters that have no means of firing or heating if there is no flow of water through the system. Therefore, DOE has tentatively concluded that a different standby loss test procedure is required for flow-activated instantaneous water heaters. To differentiate units for which the proposed standby loss test procedure discussed in this section will apply, DOE proposes to define "flow-activated instantaneous water heater" as set out in the regulatory text at the end of this document.

Issue 13: DOE requests comment on its proposed definition for "flow-activated instantaneous water heater." Specifically, DOE requests feedback on whether the definition includes all units and designs for which a separate standby loss test procedure is warranted, and whether any units would be included that do not need a test method separate from the current standby loss test procedure for CWH equipment.

DOE notes that the requirement to measure a "mean tank temperature" to calculate the standby loss would also be an issue for all instantaneous water heaters and hot water supply boilers that have a storage capacity of 10 gallons or more and that do not meet DOE's proposed definition of "storage-type instantaneous water heater", because these units do not have an integral tank, and the heat exchanger geometry can make obtaining an accurate reading of the water stored within the heat exchanger difficult to obtain. DOE has addressed this issue both in its proposed test method for flow-activated instantaneous water heaters contained within this section, and in proposed changes to the current standby loss test procedure for other instantaneous water heaters and hot water supply boilers discussed in section III.I of this NOPR.

To develop a new Federal standby loss test procedure for flow-activated instantaneous water heaters, DOE first reviewed the 2014 AHRI-recommended test method. After its review, DOE identified potential issues and provided AHRI with questions seeking further clarifications on various aspects of their recommended test method related to conduct of the test, duration of test, flow and temperature measurements, and the equations used to calculate standby loss. On August 17, August 18, and December 14, 2015, DOE received separate responses from AHRI members Thermal Solutions Inc., Raypak Inc. and A. O. Smith, respectively.[13] The responses provide answers to all the questions posed by DOE and clarified the intent of the 2014 AHRI-recommended test method.

In November 2015, ANSI published an updated version of the ANSI Z21.10.3 test standard. This updated version, ANSI Z21.10.3–2015, includes Annex E.3, which describes a test method for measuring the standby loss of tube-type instantaneous water heaters having a storage capacity of 10 gallons or more. DOE reviewed this section carefully and found it to be similar to the Annex E.3 included in the 2014 AHRI-recommended test method. The only difference DOE identified between the two versions of Annex E.3 was the referenced section for determining the volume of water contained in the water heater. Specifically, Annex E.3 in the 2014 AHRI-recommended test method references to section 5.27 of ANSI Z21.10.3 for determining the water contained in the water heater, while Annex E.3 of ANSI Z21.10.3–2015 references section 5.28 of ANSI Z21.10.3–2015, "Capacities of tube type water heaters." After carefully comparing the 2014 AHRI-recommended test method with Annex E.3 of ANSI Z21.10.3–2015, DOE believes that ANSI Z21.10.3–2015 renumbered section 5.27 as 5.28, and that AHRI's reference to section 5.27 was referring to the section titled "Capacities of tube type water heaters." Therefore, DOE has tentatively concluded that there are no substantive differences between the 2014 AHRI-recommended test method and the test method contained in Annex E.3 of ANSI Z21.10.3–2015.

As previously discussed, prior to the publication of ANSI Z21.10.3–2015, DOE posed several questions and sought clarifications from AHRI on various aspects of the 2014 AHRI-recommended test method. Thermal Solutions Inc., Raypak Inc., and A.O. Smith provided responses to DOE's questions. The major issues on which DOE sought clarification, along with the manufacturer responses, are described in the following paragraphs.

First, DOE sought clarification as to whether the 2014 AHRI-recommended test method applies to all tube-type (thermostatically-activated and flow-activated) water heaters with a storage capacity of 10 gallons or more, or only to flow-activated instantaneous water heaters. DOE notes that AHRI's comments indicate that the test procedure is exclusively for flow-activated instantaneous water heaters. However, the title of the 2014 AHRI-recommended test method indicates that the test applies to all "tube-type" instantaneous water heaters. (AHRI, No. 10 at p.4) Judging by the title and the language used in the test method, DOE initially interpreted the test method as divided into two distinct parts: (1) The first part pertaining to tube-type instantaneous water heaters that are thermostatically-activated and are not flow-activated;[14] and (2) the second part pertaining to water heaters that will neither initiate, nor cause actions that will initiate, burner operation based on a thermostatic control. DOE interpreted this second part of the test procedure to be applicable to flow-activated instantaneous water heaters that are not thermostatically-activated. However, the responses from Raypak and Thermal Solutions indicate that the entire 2014 AHRI-recommended test method (Annex E.3) is exclusively meant for flow-activated instantaneous water heaters. Raypak and Thermal Solutions stated that the first part of the test method is meant for water heaters that are flow-activated but may have some other form of energy-consuming function or water circulation during the conduct of the standby loss test. (Thermal Solutions, No. 11 at p 1; Raypak, No. 12 at p. 2) A.O. Smith also stated that DOE's interpretation was incorrect, and that the 2014 AHRI-recommended test method is divided into two parts to cover different designs of instantaneous water heaters whose tube type heat exchangers happen to store ten gallons or more. A.O. Smith further stated that the first part of the test method addresses instantaneous water heaters whose burners may activate by some specialty feature (*e.g.*, frost control) and the second part of the test method addresses more common designs that are installed with a remote storage tank and a thermostat that activates the water pump, which then activates the burners. A.O. Smith also stated that the first part of the 2014 AHRI-recommended test method does not address thermostatically-activated models. (A.O. Smith No. 14 at p. 1)

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[13] The response from Thermal Solutions Inc. can be found in the docket for this rulemaking at: *http://www.regulations.gov/#!documentDetail;D=EERE-2014-BT-TP-0008-0011.*

The response from Raypak Inc. can be found at: *http://www.regulations.gov/#!documentDetail;D=EERE-2014-BT-TP-0008-0012.*

The responses from A.O. Smith can be found at: *http://www.regulations.gov/#!documentDetail;D=EERE-2014-BT-TP-0008-0014.*

[14] The first equation for standby loss calculated in the first part of 2014 AHRI-recommended test method includes a term for fuel consumed. The test procedure also states that the second equation is for units for which the main burner(s) do not cycle back on during the course of the test. Based on this language, DOE interpreted the first part (that includes the first and second equation) to be for units that are thermostatically-activated and not flow-activated.

Thermal Solutions and Raypak did not comment on DOE's interpretation of the second part of the 2014 AHRI-recommended test method. However, judging by the response from A.O. Smith regarding the second part and the responses from A.O. Smith, Thermal Solutions, and Raypak regarding the first part, DOE infers that the second part of the test procedure is meant for flow-activated instantaneous water heaters that do not have any form of energy consumption or water circulation during the conduct of the standby loss test. (Thermal Solutions, No. 11 at p 1; Raypak, No. 12 at p. 2; A.O. Smith No. 14 at p. 1)

DOE also sought clarifications on the equations used to calculate the standby loss in both parts of the 2014 AHRI-recommended test method. In the first equation of the 2014 AHRI-recommended test method, DOE noticed an inconsistency in units of measurement. (AHRI, No. 10 at p. 5) When calculated, the first term of this equation has the units Btu/h, while the second term has the units 1/h. Mathematically, a subtraction or addition operation cannot be applied over two numbers that have different units of measurement. In their responses, the manufacturers also acknowledged the issues with regards to the equations for calculating standby loss and stated that AHRI has worked on a corrected derivation for the equations of this test procedure. (Thermal Solutions, No. 11 at p 3; Raypak, No. 12 at p. 4; A.O. Smith No. 14 at p. 3) DOE notes that later versions of the AHRI-recommended test methods (discussed later in this section) rectify this error in the first equation of the 2014 AHRI-recommended test method. However, the later versions of the AHRI-recommended test methods convert standby loss units from percent-per-hour of the heat content of the stored water to Btu-per-hour based on a temperature difference of the average value of the outlet water temperature minus the average value of the ambient temperature measured during the course of the test. This method of calculation does not match with the standby loss definition that is currently set forth in 10 CFR 431.102, which is based on a temperature difference of 70 °F between the stored water and the ambient air. Therefore, DOE has tentatively decided not to consider this equation for the proposed standby loss test procedure for flow-activated instantaneous water heaters.

In the second equation of the 2014 AHRI-recommended test method, DOE sought to understand the rationale for choosing a temperature difference term that is equal to the difference between the outlet water temperature and supply water temperature to calculate the thermal energy lost during the test. (AHRI, No. 10 at p. 5) In the third equation of the 2014 AHRI-recommended test method, DOE sought to understand the rationale for assuming a constant temperature difference of 70 °F between the supply water and the outlet water temperature. Further, the third equation appeared to assume that the outlet water in the water heater will cool down to the supply water temperature over a span of exactly 24 hours during the conduct of the test. (AHRI, No. 10 at p. 6) On the issue of considering the temperature difference between the outlet water temperature and supply water temperature to calculate the loss in thermal energy during the test, the manufacturers stated that AHRI has conservatively assumed the temperature of stored water inside the water heater to be equal to the outlet water temperature. The manufacturers stated that the geometry of these water heaters does not allow for the measurement of the mean stored water temperature inside the water heater. As a consequence, the commenters suggested using the outlet water temperature in place of the mean stored water temperature to carry out the standby loss calculations. (Thermal Solutions, No. 11 at pp. 3, 5; Raypak, No. 12 at pp. 4, 6; A.O. Smith No. 14 at pp. 3–5). The manufacturers also stated that they are willing to accept a conservative estimate of the standby loss in order to reduce the complexity and burden of the test method. (Thermal Solutions, No. 11 at p. 3; Raypak, No. 12 at p. 4; A.O. Smith No. 14 at p. 3–5)

DOE also sought clarification on the duration of the standby loss test. In particular, DOE sought an answer to whether any consideration was given to the possibility that flow-activated water heater burners may not cycle on at any point during the test and instead cool down completely in less than 24 hours. The manufacturers' responses to this question indicated that the suggested test method includes a one-hour test, and it is assumed that all the heat is lost in the heat exchanger. (Thermal Solutions, No. 11 at p 4; Raypak, No. 12 at p. 4; A.O. Smith No. 14 at p. 5)

Another issue that DOE sought clarification on is the method used to measure the storage volume of the water heater. Section 5.27 of ANSI Z21.10.3–2015 (that is the same as section 5.26 of ANSI Z21.10.3–2011, 2013, and 2014), "Capacities of storage vessels," describes a method of test to measure the storage volume of a water heater containing a storage vessel or with an input rating less than 4,000 Btu/h per gallon of water stored. The 2014 AHRI-recommended test method specifies using the methodology described in section 5.27 of ANSI Z21.10.3, that DOE believes corresponds to section 5.28 of ANSI Z21.10.3–2015, "Capacities of tube type water heaters." DOE reviewed section 5.28 of ANSI Z21.10.3–2015 carefully, and noticed that this section does not specify a method for determining the volume of tube-type water heaters; instead, it only states that the volume shall be determined. DOE sought clarifications on the rationale for using the test method described in section 5.28, "Capacities of tube type water heaters" of ANSI Z21.10.3–2015 as opposed to section 5.27, "Capacities of storage vessels" of ANSI Z21.10.3–2015 (that is the same as section 5.26 of ANSI Z21.10.3–2011, 2013 and 2014). Section 5.26 of ANSI Z21.10.3–2011 is used for measuring the storage volume of all CWH equipment in Exhibit G.2 of ANSI Z21.10.3–2011, which is incorporated by reference in the current Federal standby loss test procedure.

In response to this issue, the manufacturers stated that determining the stored volume using section 5.26 of ANSI Z21.10.3 (which DOE interprets as referring to section 5.26 of ANSI Z21.10.3–2011, 2013, and 2014, "Capacities of storage vessels," which corresponds to section 5.27 of ANSI Z21.10.3–2015) is only required for water heaters that are known to have a stored water capacity greater than or equal to ten gallons and that the test is not required for water heaters with less than ten gallons of storage capacity. The manufacturers' comments indicate that they believe the test method to measure the storage volume is left to the discretion of the certification body. The manufacturers further stated that the test method in section 5.26 may not be a reliable test method for water heaters with small water volumes, manifold coils, and complex geometries. Moreover, they stated that heat exchangers used in the water heaters are hydrostatically tested before the assembly, as required by the American Society of Mechanical Engineers (ASME) and will always have some residual water in the heat exchanger. According to the manufacturers, this residual water will result in inaccurate measurement of the volumetric capacity of the water heater. (Thermal Solutions, No. 11 at pp. 1–2; Raypak, No. 12 at p. 2; A.O. Smith No. 14 at pp. 1–2)

Another issue that DOE noticed with the test procedure in Annex E.3 of ANSI Z21.10.3–2015 is that (similar to the 2014 AHRI-recommended test method) the first part of Annex E.3 of ANSI Z21.10.3–2015 appears to be for thermostatically-activated units. Annex E.3 of ANSI Z21.10.3–2015 does not appear to be applicable exclusively to flow-activated instantaneous water heaters as is indicated by the manufacturers in their responses and AHRI in the 2014 AHRI-recommended test method. (AHRI, No. 10 at p. 4; Thermal Solutions, No. 11 at pp. 1; Raypak, No. 12 at pp. 1–2; A.O. Smith, No. 14 at p. 1)

On December 2, 2015, AHRI submitted another supplemental comment to the February 2014 RFI that included a revised recommendation for a test method for measuring standby loss for tube-type commercial instantaneous water heaters and hot water supply boilers that contain more than 10 gallons of water ("2015 AHRI-recommended test method"). (AHRI (2015), No. 13, pp.1, 6–8)[15] DOE compared the 2014 AHRI-recommended test method with the 2015 AHRI-recommended test method to identify the differences between the two test methods. In the 2015 AHRI-recommended test method, AHRI updated the equations for calculation of standby loss in its recommended Annex E.3. After reviewing these revised equations, DOE notes that the first equation in Annex E.3 of the 2015 AHRI-recommended test method is the result of converting the current equation for standby loss specified in Exhibit G.2 of ANSI Z21.10.3–2011 (but with the mean tank temperature replaced with the outlet water temperature) from units denominated as percentage-per-hour to units denominated as Btu-per-hour, by multiplying by a term consisting of $k \times V_a \times \Delta T_3/100$.[16] DOE also notes that the second equation provided in the 2015 AHRI-recommended test method is identical to the second equation that is provided in the 2014 AHRI-recommended test method and as stated in the test method, is used for water heaters for which the main burner(s) do not cycle on during the course of the test. The final equation in the 2015 AHRI-recommended test method specifies the time for the duration of the test as 24 hours, similar to the 2014 AHRI-recommended test method. However, in the 2015 AHRI-recommended test method, the variables used in the final equation and the variables defined after the equation are not consistent—specifically, the equation contains the term ΔT_4, while the list of variables below the equation includes ΔT_5. The final equation in the 2015 AHRI-recommended test method uses ΔT_4, while the final equation in the 2014 AHRI-recommended test method uses ΔT_5. Other than the differences mentioned in this paragraph, DOE tentatively determined that the 2015 AHRI-recommended test method contains no additional substantive differences from the previously submitted 2014 AHRI-recommended test method. Therefore, other than these differences, all issues that DOE identified with the standby loss test in the 2014 AHRI-recommended test method also apply to the 2015 AHRI-recommended test method.

On January 11, 2016, AHRI submitted a third supplemental comment to the February 2014 RFI that included a further revised recommendation for a test method for measuring standby loss for tube-type commercial instantaneous water heaters and hot water supply boilers that contain more than 10 gallons of water ("2016 AHRI-recommended test method"). (AHRI (2016), No. 13, pp.1, 6–8) After carefully reviewing this submission, DOE tentatively determined that the only difference between the 2015 AHRI-recommended test method and the 2016 AHRI-recommended test method are the temperature differences used in equations for calculating standby loss. Specifically, the temperature difference used in the first two equations in Annex E.3 of the 2016 AHRI-recommended test method is ΔT_5, which represents the difference between the final outlet water temperature and the initial outlet water temperature. This differs from the temperature difference terms used in the corresponding standby loss equations in the 2015 AHRI-recommended test method, which are denoted as ΔT_4 and defined as the difference between the average supply water temperature and the outlet temperature. In the final standby loss equation in Annex E.3, the temperature difference used is ΔT_6, which represents 70 °F, the difference between the supply and outlet water temperatures, and was previously denoted as ΔT_5 in the corresponding equation in the 2015 AHRI-recommended test method. These changes in temperature difference terms in standby loss equations help to clarify issues with these terms that DOE identified in the 2015 AHRI-recommended test method. However, with the exception of these temperature difference terms, the other issues that DOE identified with the 2014 and 2015 AHRI-recommended test methods also apply to the 2016 AHRI-recommended test method.

DOE has considered the initially submitted 2014 AHRI-recommended test method, the clarifications provided by manufacturers, Annex E.3 of the recently published ANSI Z21.10.3–2015, and the recently submitted 2015 and 2016 AHRI-recommended test methods in developing the proposed standby loss test procedure for flow-activated instantaneous water heaters. DOE agrees with certain aspects of the recommended test methods and the related clarifications; however, DOE tentatively concludes that there are several modifications that need to be made to the 2016 AHRI-recommended test method for it to be used as a Federal standby loss test procedure for flow-activated instantaneous water heaters. As noted previously, the only difference between the 2016 AHRI-recommended test method and Annex E.3 of ANSI Z21.10.3–2015 is with regards to the first equation in both test methods and, similarly, DOE is not proposing to adopt the test method in Annex E.3 as the Federal test method. Rather, the following paragraphs describe DOE's proposed test method, including differences from both the 2016 AHRI-recommendation and the ANSI Z21.10.3–2015 test method, and the reasons such changes are deemed necessary.

As previously defined in this section, a flow-activated instantaneous water heater will initiate firing or heating only when water is being drawn from the water heater. In Annex E.3 of ANSI Z21.10.3–2015 and the 2016 AHRI-recommended test method, the water heater is kept in standby mode, and no hot water is drawn from the equipment during the standby loss test. Under such conditions, the water heater would not be expected to initiate burner or heating element operation at any point during the course of the test since there is no flow to activate the heat source. As a result, hot water stored in the water heater in standby mode will continuously lose heat to the environment until the water temperature approaches the surrounding ambient air temperature. DOE considers this standby mode operation for flow-activated instantaneous water heaters to be characteristically different from the standby mode operation of thermostatically-activated water heaters, where the main burner or element(s) cycles on when the water temperature drops below the thermostat set point.

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[15] DOE received two supplemental comments from AHRI in response to the February 2014 RFI on December 2, 2015 and January 11, 2016. Both comments are included in the docket under filing number EERE–2014–BT–TP–0008–0013. To differentiate between the two documents for citations, DOE uses "AHRI (2015)" and "AHRI (2016)" to refer to the comment received on December 2, 2015 and on January 11, 2016, respectively. Both supplemental comments can be found at: *http://www.regulations.gov/#!documentDetail;D=EERE-2014-BT-TP-0008-0013.*

[16] Annex E.2 of ANSI Z21.10.3–2013 (and 2014) defines 'K' as the nominal specific heat of water that has a value of 8.25 Btu per gallon. This is the same as 'k' that is used by AHRI in their equations in the Annex E.3 of the 2015 and 2016 AHRI-recommended test method. The term Va refers to the measured volume expressed in gallons and measured as per section 5.27 of ANSI Z21.10.3–2015 and ΔT_3 refers to the difference between the average value of the outlet water temperature and the average value of the ambient temperature expressed in °F.

The first part of Annex E.3 of ANSI Z21.10.3–2015 and the 2016 AHRI-recommended test method appears to apply to water heaters that may circulate water or initiate some other energy-consuming function when hot water is not being drawn. If a water heater consumes energy for the purpose of heating water during the standby mode, then such a water heater would not fit the proposed definition of a "flow-activated instantaneous water heater." Such water heaters would instead be covered by the proposed standby loss test method for instantaneous water heaters and hot water supply boilers that are not flow-activated, as discussed in section III.I of this NOPR. However, to account for other types of fuel consumption during standby mode (*i.e.*, other than directly for the purpose of heating water), DOE has retained the fuel consumption terms in the proposed standby loss equation for flow-activated instantaneous water heaters.

The driving temperature difference that causes the constant heat loss to the ambient air from the water heater is the difference between the stored water and the ambient air temperature. This temperature difference must be factored into the standby loss calculations, as included in the 2016 AHRI-recommended test method, instead of the temperature difference between outlet and supply water that is used in Annex E.3 of ANSI Z21.10.3–2015 and the 2015 AHRI-recommended test method. In addition, the current standby loss test procedure that is set forth in Exhibit G.2 of ANSI Z21.10.3–2011 (incorporated by reference into the current DOE test procedure) calculates the standby loss as a percentage per hour of the total heat content of the water heater. In DOE's test procedure for gas-fired and oil-fired CWH equipment as set forth in 10 CFR 431.106, DOE uses this percent-per-hour standby loss value to calculate the standby loss in terms of Btu/h based on the storage volume and a 70 °F temperature difference between the stored water and the ambient air temperature. DOE notes that the 2016 AHRI-recommended test method converts from standby loss in terms of percent-per-hour to standby loss in terms of Btu-per-hour by multiplying by a term that includes ΔT_3, which is defined in Annex E.3 of ANSI Z21.10.3–2015 as the difference between the outlet water temperature and the average value of the ambient temperature. This is in contrast to: (1) DOE's current test procedure as specified in 10 CFR 431.106, which converts using a fixed 70 °F temperature difference rather than using the measured temperature difference from testing and, (2) the current definition of "standby loss" specified in 10 CFR 431.102 that defines "standby loss" as the average energy required to maintain the stored water temperature, expressed in Btu per hour based on a 70 °F temperature differential between stored water and ambient temperature.

DOE notes that use of a fixed 70 °F temperature difference allows for straightforward conversion of standby loss from one set of units to another, while use of the measured temperature difference requires the availability of data from efficiency testing. DOE sees value in such a straightforward conversion, so that those without access to efficiency test data can still convert between the two values. Additionally, the standby loss test method that is proposed for flow-activated instantaneous water heaters already takes into account the measured temperature difference between the outlet water temperature and the ambient air temperature, making the additional inclusion of this term in the conversion unnecessary. Finally, use of a constant 70 °F temperature difference would make the conversion in this proposed standby loss test procedure consistent with that in DOE's current test procedure at 10 CFR 431.106, and DOE also proposes this method of conversion to standby loss in terms of Btu/h for other classes of gas-fired and oil-fired CWH equipment in appendices A and C to subpart G of 10 CFR part 431. Therefore, DOE proposes to use the same approach of a constant 70 °F temperature difference to calculate the standby loss for gas-fired and oil-fired flow-activated instantaneous water heaters. For electric flow-activated instantaneous water heaters, DOE proposes to maintain a standby loss metric in terms of a percent-per-hour value.

As discussed in this preamble, the 2016 AHRI-recommended test method specifies setting a time duration of one hour for flow-activated water heaters that would not have any form of energy consumption to maintain the water temperature and that would eventually cool down to ambient temperature. DOE sees merit in setting a maximum time duration to mark the end of the test. However, DOE does not agree with having the time duration as the only criterion for ending the standby loss test. As noted previously, the standby loss test for flow-activated instantaneous water heaters resembles a constant cool down test where the main burner or heating element does not cycle on at any point in the course of the test. For these water heaters, it is very likely that the stored water in the unit cools down to the ambient temperature before 24 hours. In such a scenario, from the time the stored water temperature reaches the ambient temperature to the end of the 24 hours, the water heater will not experience any standby energy loss. However, the standby loss equation provided in the 2016 AHRI-recommended test method assumes that the entire heat loss takes place over a duration of 24 hours. As a result, using the 2016 AHRI-recommended test method, the standby loss value calculated for water heaters that cool down before the 24-hour time period would understate the actual hourly heat loss from the water heater. Based on the 2016 AHRI-recommended test method, two water heaters that have the same storage volume and electricity consumption but different cooling rates as they both cool down to the ambient temperature within 24 hours would have the same standby loss value. DOE has determined that this would lead to an inaccurate comparison of the standby loss between two water heaters that lose heat at different rates. A similar issue would arise if the time duration were set to one hour or any specific value that might be less than the time it takes some water heater to cool to ambient temperature, because such a time criterion would capture the heat loss to different final water temperatures for different water heaters (*i.e.*, two different water heaters would have different final water temperatures at the end of the set time period). This variation in final water temperature would impart an undesirable benefit to water heaters that lose heat more quickly, because the rate of heat transfer from water to the surrounding air decreases as the corresponding temperature difference decreases.

To avoid these issues and to compare standby loss of different water heaters with a more consistent approach, DOE proposes to use a temperature criterion in addition to a fixed maximum time duration to mark the end of the test. DOE proposes that the standby loss test be stopped at the first instance that the measured outlet water temperature is 35 °F below the outlet water temperature measured at the start of the test. If the specified temperature drop in the outlet water temperature does not occur within a 24 hour time period then the test shall be stopped at the end of 24 hours from the start of the test.

Finally, DOE must specify a method for determining the storage volume of the water heater. The manufacturers' responses stated that for some water heaters, it will not be necessary to measure the volume if it is less than 10 gallons. Although DOE does not currently prescribe a standby loss standard for instantaneous water heaters and hot water supply boilers with a storage volume below 10 gallons, DOE requires certification of the rated storage volume for all gas-fired and oil-fired instantaneous water heaters and hot water supply boilers. These certification requirements are set forth at 10 CFR 429.44(c)(2)(iv) and (v).

Because flow-activated instantaneous water heaters have heat exchanger designs similar to thermostatically-activated instantaneous water heaters, the issue of measuring the storage volume applies to all instantaneous water heaters and hot water supply boilers. Exhibit G.2 of ANSI Z21.10.3–2011 (that is incorporated by reference into the current DOE test procedure) references section 5.26 of the same testing standard as a method to measure the storage volume of CWH equipment. In response to the February 2014 RFI, HTP raised an issue with regards to the measurement of storage volume for instantaneous water heaters and hot water supply boilers. HTP commented that due to various geometries and sizes, measurement of the storage volume by a third-party laboratory or manufacturer's facility would be difficult and may produce inconsistent results. (HTP, No. 5 at p. 2) As discussed earlier, this issue was also raised by manufacturers in response to DOE's questions on the 2014 AHRI-recommended standby loss test method for flow-activated instantaneous water heaters.

DOE acknowledges the issues highlighted by manufacturers regarding use of section 5.26 of ANSI Z21.10.3–2011 (which corresponds to section 5.27 of ANSI Z21.10.3–2015) to measure the storage volume of instantaneous water heaters and hot water supply boilers, including flow-activated and thermostatically-activated units. To find alternatives to this test method, DOE investigated other options for measuring the storage volume of such water heaters. Through its review, DOE did not identify an alternative test method suitable to measure the storage volume of instantaneous water heaters and hot water supply boilers that would not significantly increase the testing burden for manufacturers. Moreover, section 5.28, "Capacities of tube type water heaters," of ANSI Z21.10.3–2015 does not specify a test method to measure the storage volume. Instead, section 5.28 of ANSI Z21.10.3–2015 only states that the "volume contained in the water heater shall be determined." The wording of this section and the manufacturers' responses on this test method appear to suggest that the actual method of determination of the volume is left to the discretion of the testing agency.

The test method in section 5.27 of ANSI Z21.10.3–2015 requires the water heater to be weighed dry and empty, and then reweighed when filled with water. The difference in the two values of the weight equate to the weight of the stored water in the water heater. The weight of stored water can be converted into gallons by dividing by the density of water. Although section 5.27 of ANSI Z21.10.3–2015 specifically states that the test be used for storage vessels or water heaters having an input rating of less than 4,000 Btu/h per gallon of capacity, the test method appears to be applicable to any CWH equipment that can be weighed both dry and after being filled with water. The energy conservation standards for instantaneous water heaters are dependent on the rated storage volume. The rated storage volume is needed to determine the appropriate equipment class and, for units with storage volume greater than or equal to 10 gallons, it is required to calculate the standby loss standard. Therefore, DOE must specify a test method to measure the storage volume of water heaters, rather than leave the decision of the appropriate method (*e.g.*, direct measurement, calculation) to individual manufacturers or testing agencies, who may choose different methods for determining the storage volume, which could provide inconsistent results. Based on the foregoing reasoning, and the lack of alternative test methods to measure the storage volume, DOE tentatively concluded that the method presented in section 5.27 of ANSI Z21.10.3–2015 should be used for measurement of the storage volume of instantaneous water heaters and hot water supply boilers that do not meet DOE's proposed definition for "storage-type instantaneous water heater," including thermostatically-activated and flow-activated instantaneous water heaters. However, because section 5.27 of ANSI Z21.10.3–2015 includes a limitation that the method is only applicable to units containing storage vessels, DOE proposes not to incorporate this section by reference, and instead proposes a test procedure very similar to the method in section 5.27 of ANSI Z21.10.3–2015, with only clarifying changes. Specifically, DOE proposes to remove the limitation that only storage vessels or water heaters having an input rating of less than 4,000 Btu/h per gallon of capacity can be tested using this method, and clarifies that the density of water at the measured water temperature is to be used to convert from the weight of water to the volume in gallons.

Issue 14: DOE requests comment on its proposal to include a test procedure similar to that specified in section 5.27 of ANSI Z21.10.3–2015 for measuring the storage volume of all instantaneous water heaters and hot water supply boilers, including flow-activated instantaneous water heaters. DOE also seeks information on alternative methods for measuring storage volume and the impact of residual water on measuring storage volume of instantaneous water heaters and hot water supply boilers. Further, DOE seeks comment on ways to remove residual water from the water heater that could allow for more accurate and consistent measurement of the storage volume of CWH equipment.

Based on the AHRI-recommended test methods and the responses received from manufacturers, DOE proposes a new standby loss test procedure for flow-activated instantaneous water heaters. The proposed test procedure is based on the 2016 AHRI-recommended test method, specifically the second part of the test method that applies to flow-activated water heaters that will not initiate burner operation over the course of the test. However, in developing the proposed test method, DOE has departed from the 2016 AHRI-recommended test method in several areas, including the method of test, time duration, and equations to calculate standby loss. DOE also conducted investigative testing on flow-activated instantaneous water heaters that helped inform the proposals made to this test procedure. The following paragraphs describe DOE's proposed test method for measuring the standby loss of flow-activated instantaneous water heaters. The proposed test procedure is also included in the proposed regulatory text for appendix E to subpart G of part 431.

The proposed standby loss test for flow-activated instantaneous water heaters can be started immediately after the thermal efficiency test, using the same test set-up and test conditions. Otherwise, if the standby loss test is conducted separately, install the water heater as per the specifications in section 2 of appendix E to subpart G of part 431. As discussed in section III.H, DOE proposes required locations for temperature-sensing instrumentation for instantaneous water heaters and hot water supply boilers, including flow-activated instantaneous water heaters. For water heaters with multiple outlet water connections leaving the water heater jacket, apply the test set-up provisions proposed in section III.H (also included in appendix C to subpart G of part 431). The representative value of the outlet water temperature used for the standby loss calculations is obtained by taking the average of the water temperatures measured at each water connection leaving the water heater jacket. DOE proposes that the test entity set the data acquisition system to record the supply water temperature, outlet water temperature, ambient room temperature, and electrical consumption (as applicable) at intervals of every 30 seconds.

DOE proposes the test be conducted as follows:

Once the water heater is set up, supply water to the equipment being tested as per section (d) of Annex E.1 of ANSI Z21.10.3–2015. Adjust the water flow rate in such a way that the outlet water reaches a temperature of 70 °F ± 2 °F above the supply water temperature. After the outlet water temperature has remained constant with no variation of more than 2 °F over a 3-minute period and maintains a temperature of 70 °F ± 2 °F above the supply water temperature, turn off the supply and outlet water valves that are installed closest to the water heater (as per the provisions in appendix C to subpart G of part 431), and the water pump, simultaneously. Allow the water heater to cut-out. Immediately after the cut-out, begin recording measurements for the standby loss test.

At this time, start the clock and record the initial outlet water temperature, ambient room temperature, and fuel (and electricity) meter reading. Continue to monitor and record the outlet water temperature, the ambient room temperature, the time elapsed from the start of the test, and the electricity consumption at 30-second intervals using a data acquisition system.

Stop the test if the outlet water temperature decreases by 35 °F from the initial outlet water temperature within 24 hours from the start of the test. Record the final outlet water temperature, final ambient room temperature, fuel consumed, electricity consumed, and the time elapsed from the start of the test.

If the outlet water temperature does not decrease by 35 °F from the initial outlet water temperature within 24 hours from the start of the test, then stop the test after 24 hours from the start of the test. Record the final outlet water temperature, final ambient room temperature, fuel consumed, electricity consumed, and the time elapsed from the start of the test.

Use the equation below to calculate the standby loss in terms of percent of total heat content per hour.

$$S = \frac{\dfrac{k(V_a)(\Delta T_1)}{E_t/100} + E_c + (C_s)(Q_s)(H)}{k(V_a)(\Delta T_2)(t)} \times 100\%$$

Where,

ΔT_1 = Outlet water temperature measured at the start of the test minus outlet water temperature measured at the end of the test, expressed in °F

ΔT_2 = Outlet water temperature at the start of the test minus the ambient room temperature at the start of the test, expressed in °F

k = 8.25 Btu/gallon·°F, the nominal specific heat of water

V_a = Volume of water contained in the water heater in gallons

E_t = Thermal efficiency of the water heater. For electric water heaters with immersed heating elements use 98 percent.

E_c = Electrical energy consumed by the water heater during the duration of the test in Btu

C_s = Correction applied to the heating value of a gas H, when it is metered at temperature and/or pressure conditions other than the standard conditions upon which the value of H is based. C_s is not applicable to oil-fired equipment.

Q_s = Total fuel flow as metered for gas-fired and oil-fired equipment, expressed in ft^3 (gas) or lb (oil)

H = Higher heating value of gas, expressed in Btu/ft^3 (gas) or Btu/lb (oil)

t = Total duration of the test in hours

S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the initial heat content of the stored water above room temperature

For gas-fired and oil-fired flow-activated instantaneous water heaters, to calculate the standby loss in terms of Btu per hour, use the following equation:

$SL = S\% \times K(V_a)(70\ °F)$

Where, SL refers to the standby loss of the water heater, defined as the amount of energy required to maintain the stored water temperature expressed in Btu per hour.

Issue 15: DOE requests comment from interested parties on all aspects of the proposed test procedure for flow-activated instantaneous water heaters. Specifically, DOE requests comment on its tentative decision to: (1) Base the test procedure on the second part of the 2016 AHRI-recommended test method that applies to flow-activated water heaters that will not initiate burner operation over the course of the test; (2) stop the test following a 35 °F ± 2 °F drop in the outlet water temperature or completion of 24 hours, whichever occurs earlier; and (3) use the outlet water temperature as an approximation of the stored water temperature.

H. Test Set Up for Commercial Instantaneous Water Heaters and Hot Water Supply Boilers

The current thermal efficiency and standby loss test methods as described in ANSI Z21.10.3–2011 require commercial instantaneous water heaters and hot water supply boilers to be set up in accordance with Figure 2 of that test standard. Although the figure is not drawn to scale and no measurements are specified, DOE notes that the temperature-sensing instruments for measuring outlet water temperature appear to be placed at a considerable distance away from the water heater being tested. Measuring the temperature at a significant distance away from the water heater could lead to an inaccurate representation of the outlet water temperature due to heat loss in the piping. Even if the pipes are insulated, measuring temperature as close as possible to the outlet ports or possibly inside the port would yield a more accurate representation of the outlet water temperature. The heat loss from the piping would be higher while conducting the standby loss tests that could run for several hours to a maximum of 24 hours for flow-activated instantaneous water heaters and from 24 to 48 hours for other instantaneous water heaters and hot water supply boilers. Moreover, the new standby loss test procedure that is proposed for flow-activated instantaneous water heaters in this NOPR uses the outlet water temperature as an approximation for the stored water temperature inside the water heater. Therefore, it is important that the outlet water temperature be measured as close as possible to the water heater to minimize the effect of piping heat losses while conducting the standby loss test.

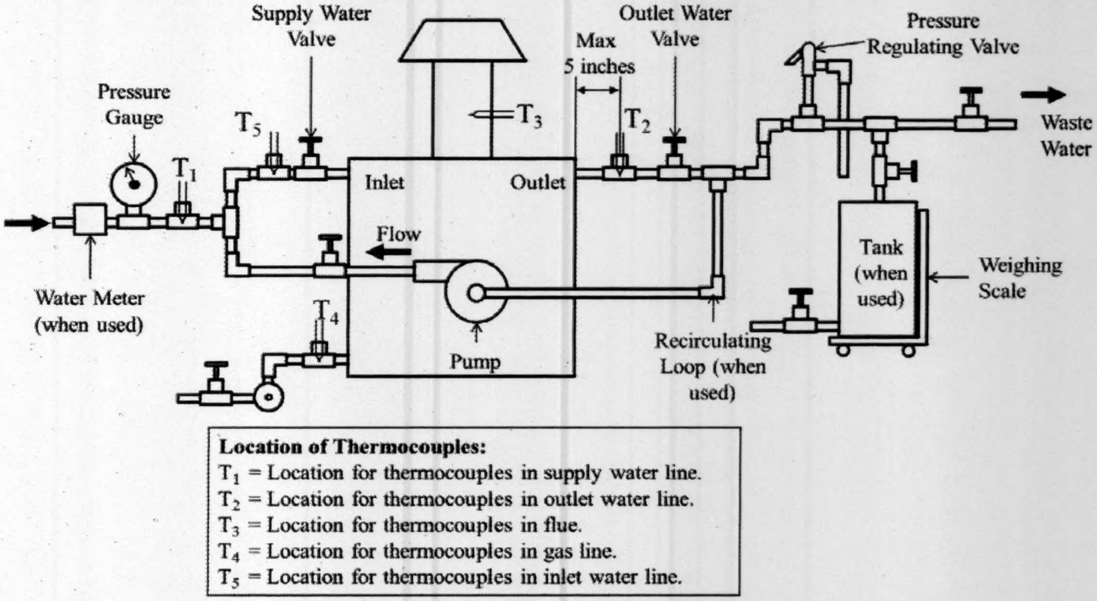
To address these issues, DOE proposes to specify the location and a set of requirements for placement of the temperature sensors to ensure that they accurately represent the outlet water temperature for the CWH equipment. Specifically, DOE proposes that the tip or junction of the temperature sensor be placed: (1) In the water; (2) less than or equal to 5 inches away from the water heater jacket; (3) about the central axis of the water pipe; and (4) with a radiation protection shield. The type and number of temperature-sensing instruments is left to the discretion of the testing operator.

Certain instantaneous CWH models have multiple outlet water connections leaving the jacket that are combined externally using common piping. For such units, DOE proposes that the temperature sensor placement conditions as proposed in the paragraph above be applied to each outlet water connection leaving the water heater jacket. To clarify, DOE proposes that for each outlet water connection leaving the water heater jacket, the temperature sensor be placed: (1) in the water; (2) less than or equal to 5 inches away from the water heater jacket; (3) about the central axis of the water pipe; and (4) with a radiation protection shield. For obtaining a single outlet water temperature value that is representative of the entire water heater, DOE proposes to take the average of the all outlet water temperature measurements (for each outlet water connection leaving the water heater jacket) for each recording of the data-acquisition unit. In addition to these provisions, DOE also proposes that while verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency test, the water temperatures recorded for each outlet water connection leaving the water heater jacket must: (1) Be maintained at 70 °F ± 2 °F above the supply water temperature, and (2) not differ from each other by more than 2 °F.

Figure III.4, an adaptation of Figure 3 of ANSI Z21.10.3–2015, shows DOE's proposed location requirements for the temperature-sensing instruments for measuring the inlet and outlet water temperature of instantaneous water heaters (other than storage-type instantaneous water heaters) and hot water supply boilers.

The current test procedure for instantaneous water heaters and hot water supply boilers does not clearly indicate the location and installation of the supply and outlet water valves. To obtain accurate measurements during standby operation, the water supply must be cut off to prevent mixing of water in the piping lines with that in the water heater during the standby loss test. To address this issue, DOE proposes to require supply and outlet water valves to be installed within a specified distance of the water heater. Specifically, for instantaneous water heaters and hot water supply boilers shipped without external piping installed at the point of manufacture, DOE proposes to require the supply water valve to be installed within 5 inches of the jacket, and the outlet water valve to be installed within 10 inches of the jacket. For instantaneous water heaters and hot water supply boilers with external piping assembled at the manufacturer's premises prior to shipment, DOE proposes to require the supply and outlet water valves to be installed within 5 inches of the end of the piping shipped with the unit. DOE also proposes that the supply and outlet water valves be used to turn off the water flow at the start of the standby loss test for instantaneous water heaters and hot water supply boilers (including "flow-activated instantaneous water heaters"). Figure III.4 shows the location of the valves with respect to other instrumentation used in the test set-up for units shipped without external water piping installed.

The current Federal thermal efficiency test as set forth in 10 CFR 431.106, incorporates by reference Exhibit G.1 of ANSI Z21.10.3–2011, which requires the supply water temperature to be 70 °F ± 2 °F and the outlet water temperature to be 70 °F ± 2 °F above the supply water temperature with the burner or heating element operating at its full firing rate. Certain instantaneous water heaters and hot water supply boilers, including flow-activated instantaneous water heaters that are designed to operate at higher inlet water temperatures, may not be able to achieve such a temperature rise. The current test procedure addresses this issue by allowing for the use of a recirculating loop (see Figure 3 of ANSI Z21.10.3–2015). Section 5.1.7 of ANSI Z21.10.3–2015 (which contains Figure 3) also requires that the specified inlet water temperature shall not be less than 70 °F or more than 120 °F. In this NOPR, DOE proposes to retain the option of using a recirculating loop and the limits on the inlet water temperature for instantaneous water heaters and hot water supply boilers that are not able to meet the outlet water temperature requirement at the full firing rate. DOE proposes to explicitly state the conditions for using a recirculating loop (*i.e.,* that the unit under test is unable to meet the outlet temperature at the full firing rate) and to specify the limits set on the inlet water temperature (measured at T_5), as contained in section 5.1.7 of ANSI Z21.10.3–2015. Figure III.4 shows the arrangement for optional use of a recirculating loop. DOE proposes to clarify that the supply water temperature measured at T_1 must be maintained at 70 °F ± 2 °F during the entire course of the thermal efficiency test (as applicable) and prior to starting the standby loss test, while the temperature measurement at T_5 must not be less than 70 °F or more than 120 °F.



Location of Thermocouples:

T_1 = Location for thermocouples in supply water line.
T_2 = Location for thermocouples in outlet water line.
T_3 = Location for thermocouples in flue.
T_4 = Location for thermocouples in gas line.
T_5 = Location for thermocouples in inlet water line.

Figure III.4 Installation and set-up of instantaneous water heaters (other than storage-type) and hot water supply boilers for thermal efficiency and standby loss test methods. (Adapted from Figure 3 of ANSI Z21.10.3-2015)

Figure III.4 and the proposed specifications for the placement of temperature sensors, placement of water valves, and placement of a recirculating loop (when used) are included in appendix C to subpart G of part 431.

Issue 16: DOE seeks comment on its proposed change to the location of temperature measurement for the outlet water temperature with the associated conditions for placement of temperature-sensing instruments in water pipes, as well as the placement of the supply and outlet water valves. Specifically, DOE requests comment on whether such a change would provide more accurate test results, and whether the change would be burdensome to manufacturers. Additionally, DOE requests information on any alternative arrangements to measure the outlet water temperature accurately and in close proximity to the hot water outlet of the tested CWH equipment.

I. Changes to the Standby Loss Test for Instantaneous Water Heaters and Hot Water Supply Boilers Other Than Flow-Activated Instantaneous Water Heaters

Currently, all instantaneous water heaters and hot water supply boilers having a storage capacity of ten gallons or more are required to be tested for standby loss as per the test method in Exhibit G.2 of ANSI Z21.10.3–2011, which is incorporated by reference into DOE's current test procedure. In the February 2014 RFI, DOE sought comments on the repeatability of thermal efficiency and standby loss test methods included in the ANSI Z21.10.3–2011 and ANSI Z21.10.3–2013 test methods. 79 FR 10999, 11001–02 (Feb. 27, 2014). DOE discussed the comments received in response to this issue generally in section III.B of this NOPR. In its response to this issue, HTP stated that currently, there is no standby loss test method that is suitable for hot water supply boilers containing ten gallons or more of stored water. (HTP, No. 5 at p. 2) While responding to a different issue related to the applicability of standby loss test procedure to flow-activated water heaters, AHRI commented that the current standby loss test procedure is designed for tank-type water heaters which are thermostatically-activated. (AHRI, No. 2 at p. 4)

DOE reviewed the comments made by HTP and AHRI with regards to the standby loss test procedure for instantaneous water heaters and hot water supply boilers. DOE notes that the equation used to calculate standby loss in DOE's test method for instantaneous water heaters and hot water supply boilers (as specified in Exhibit G.2 of ANSI Z21.10.3–2011) uses two temperature differential terms that both include the measurement of the mean tank temperature taken during the course of the test. To calculate the standby loss of CWH equipment, the current Federal test method requires parameters to be measured that allow for the calculation of: (1) The amount of energy consumed to maintain the stored water at the required temperature during standby mode; (2) the heat lost to the atmosphere from the stored water; and (3) the change in total heat content of the water heater between the start and the end of the test. Both the terms described in (2) and (3) are calculated using the stored water temperature, which are represented in DOE's current test method by the mean tank temperature measured during the standby loss test. Instantaneous water heaters and hot water supply boilers that do not meet DOE's proposed definition for "storage-type instantaneous water heater" (see section III.F of this document) are generally not equipped with an integral hot water storage tank, but rather, the stored water is contained within the heat exchanger. Unlike storage water heaters and storage-type instantaneous water heaters, these instantaneous water heaters and hot water supply boilers generally have water-tube heat exchangers[17] and do not store water at a uniform temperature in the heat exchanger. Due to complex heat exchanger geometries, an accurate measurement of the mean temperature of water stored within the heat exchanger is often difficult or impossible to obtain. As a result, DOE has tentatively concluded that modifications to the standby loss test method are warranted for instantaneous water heaters and hot water supply boilers that have a storage capacity of ten gallons or more, but that do not meet DOE's proposed definition for "storage-type instantaneous water heater." In this NOPR, DOE proposes a separate standby loss test procedure in section III.G for flow-activated instantaneous water heaters, which have no means of burner or heating element activation unless hot water is drawn. In this section (*i.e.,* section III.I), DOE proposes a new standby loss test procedure for instantaneous water heaters and hot water supply boilers. This proposed test procedure would only apply to instantaneous water heaters and hot water supply boilers that do not meet DOE's proposed definitions for "storage-type instantaneous water heater" or "flow-activated instantaneous water heater." The proposed test procedure is also specified in appendices C and D to subpart G of part 431.

DOE encountered the same issue for flow-activated water heaters and addressed this problem in the proposed test procedure described in section III.G. While thermostatically-activated instantaneous water heaters and hot water supply boilers differ from flow-activated instantaneous water heaters in their mechanism to initiate burner or heating element operation, these two kinds of equipment share similar heat exchanger geometries and designs. In section III.G of this rulemaking, DOE discusses the responses received from manufacturers on this issue for the standby loss test method for flow-activated instantaneous water heaters. In summary, manufacturers suggested that a measurement of the outlet water temperature could be used as an approximation of the mean stored water temperature within the heat exchanger for the purpose of calculating standby loss. Due to the similarity in heat exchanger design between flow-activated and thermostatically-activated instantaneous water heaters and hot water supply boilers, DOE has tentatively concluded that the same rationale would apply for thermostatically-activated instantaneous water heaters and hot water supply boilers (*i.e.,* a measurement of the outlet temperature can be used as a reasonable approximation of the mean stored water temperature within the heat exchanger for the purpose of calculating standby loss for thermostatically-activated instantaneous water heaters and hot water supply boilers). Therefore, DOE proposes to use the outlet water temperature as measured by the outlet water temperature sensor, instead of the mean tank temperature, to approximate the stored water temperature for the purpose of calculating standby loss for instantaneous water heaters and hot water supply boilers that do not meet DOE's proposed definition for "storage-type instantaneous water heater," including flow-activated instantaneous water heaters.

DOE also considered several other options to calculate or measure the average stored water temperature (*e.g.,* using the average of the supply and outlet water temperature, inserting thermocouples inside the heat exchanger through the outlet port of the water heater, or using heat transfer equations to back calculate stored water temperature from the heat exchanger tube wall temperature). DOE has tentatively concluded that none of the other options considered would provide an accurate measurement of the average stored water temperature inside the water heater. Moreover, because of the complex heat exchanger geometry, there would be significant difficulty involved in attempting to calculate the average stored water temperature.

DOE is also aware that in many applications, instantaneous water heaters or hot water supply boilers are used to supply hot water to an external tank where the water is stored at a fixed temperature. In these applications, a thermostat is often used to maintain the desired water temperature in the external tank as part of a recirculation loop. If the water temperature in the tank falls below the set point, then the thermostat directs the water heater to cycle on, and the recirculation pump circulates water throughout the loop, withdrawing water from the tank, and resupplying heated water back into the tank. While reviewing the standby loss test procedure for its applicability to thermostatically-activated instantaneous water heaters and hot water supply boilers, DOE considered the option of specifying an external UFHWST with specific characteristics (*e.g.,* insulation, storage volume) to be able to calculate the mean tank temperature. However, DOE has tentatively decided not to use this approach to conduct the standby loss test for thermostatically-activated instantaneous water heaters because it would also include the standby loss that occurs in the external tank and therefore, would not be representative of the water heater itself. Therefore, DOE has decided not to use an external tank to measure the mean tank temperature to conduct the standby loss test for thermostatically-activated instantaneous water heaters and hot water supply boilers.

Based on the discussion above, DOE proposes the following test procedure for determining the standby loss of instantaneous water heaters and hot water supply boilers (except for those that meet the proposed definition of a "storage-type instantaneous water heater" and "flow-activated instantaneous water heater"). This proposal includes some language from Annex E.2 of ANSI Z21.10.3–2015.

The proposed standby loss test method for instantaneous water heaters and hot water supply boilers (except those meeting the definition of "storage-type instantaneous water heater" and "flow-activated instantaneous water heater") can be started immediately after the thermal efficiency test, using the same test set-up and test conditions. Otherwise, if the standby loss test is conducted separately, one would install the water heater as per Figure III.4 in section III.H of this rulemaking (Figure 4 in appendix C to subpart G of part 431) and section 2 of appendix C or D (as applicable) to subpart G of part 431 to set up the water heater for testing. As discussed in section III.H, DOE proposes required locations for temperature-sensing instrumentation and water valves for all instantaneous water heaters and hot water supply boilers, including flow-activated instantaneous water heaters, but excluding storage-type instantaneous water heaters. For water heaters with multiple supply or outlet water connections entering the water heater jacket, apply the outlet water temperature sensor and water valves placement provisions proposed in section III.H to each pipe connection entering or leaving the water heater. The representative value of the outlet water temperature used for the standby loss calculations is obtained by taking the average of the water temperatures measured at each water connection leaving the water heater jacket.

DOE proposes that the test be conducted as follows:

Once the water heater is set up, open the flow valves, start the water pump, open the gas supply valves (as applicable), and then initiate the ignition process. After the water heater starts with the initiation of burner or heating element operation, monitor the supply and outlet water temperatures. Adjust the water flow rate in such a way that the outlet water temperature reaches a temperature of 70 °F ± 2 °F above the supply water temperature. Once this temperature is achieved, maintain the flow rate and keep monitoring the outlet water temperature. After the outlet water temperature has remained constant with no variation of more than 2 °F over a 3-minute period, turn off the water supply and outlet valves and, if necessary, the water pump. The fuel supply must be kept on for the entire duration of the test for gas-fired and oil-fired equipment. After the first cut-out, allow the water heater to remain in standby mode until the next cut-out.

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[17] By water-tube heat exchangers, DOE refers to a heat exchanger where water flows inside heat exchanger tubes and is heated by an external source of energy.

At this point, start the clock and record the initial outlet water and ambient room temperatures. Keep recording the outlet water temperature, the ambient room temperature, the time elapsed from the start of the test, the electricity consumption, and the fuel consumption at an interval of 30 seconds (as proposed in this rulemaking and discussed in section III.B) using a data acquisition system.

The duration of this test will be the earlier of: (1) The first cut-out that occurs after 24 hours or (2) 48 hours.

At the conclusion of the test, record the total fuel flow, electricity consumption, the final ambient room temperature, the time duration in hours rounded to the nearest one hundredth of an hour, and the final outlet water temperature.

Use the equation below to calculate the standby loss in terms of percent of total heat content per hour.

$$S = \frac{E_c + (C_s)(Q_s)(H) - \left(\dfrac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

Where,

ΔT_3 = Average value of outlet water temperature minus the average value of the ambient room temperature, expressed in °F

ΔT_4 = Final outlet water temperature measured at the end of the test minus the initial outlet water temperature measured at the start of the test, expressed in °F

k = 8.25 Btu/gallon·°F, the nominal specific heat of water

V_a = Volume of water contained in the water heater in gallons

E_t = Thermal efficiency of the water heater. For electric water heaters with immersed heating elements use 98 percent.

E_c = Electrical energy consumed by the water heater during the duration of the test in Btu

t = Total duration of the test in hours

C_s = Correction applied to the heating value of a gas H, when it is metered at temperature and/or pressure conditions other than the standard conditions upon which the value of H is based. C_s is not applicable to oil-fired equipment.

Q_s = Total fuel flow as metered for gas-fired and oil-fired equipment, expressed in ft^3 (gas) or lb (oil).

H = Higher heating value of gas, expressed in Btu/ft^3 (gas) or Btu/lb (oil)

S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the heat content of the stored water above room temperature

The standby loss expressed in Btu per hour must be calculated as follows: SL (Btu per hour) = S (% per hour) × 8.25 (Btu/gal-°F) × Measured Volume (gal) × 70 (degrees F).

Issue 17: DOE requests comment on the proposed test procedure for instantaneous water heaters and hot water supply boilers (except those meeting the proposed definition of "storage-type instantaneous water heater" and "flow-activated instantaneous water heater"). DOE also requests feedback on its tentative decision to use the outlet water temperature instead of the mean tank temperature or stored water temperature to conduct the standby loss test. Further, DOE requests suggestions on methods or approaches that can be used to measure the stored water temperature accurately.

J. Test Procedure for Rating Commercial Heat Pump Water Heaters

In the February 2014 RFI, DOE raised an issue with regards to implementing a new test procedure for commercial heat pump water heaters (CHPWHs). 79 FR 10999, 11003 (Feb. 27, 2014). Currently, DOE does not have a test procedure for commercial heat pump water heaters (although a section is reserved at 10 CFR 431.107). Additionally, DOE does not currently have a definition for "commercial heat pump water heater," as would help classify such units. Therefore, DOE proposes the following definition for commercial heat pump water heaters that includes air-source, water-source, and direct geo-exchange CHPWHs.

Commercial heat pump water heater (CHPWH) means a water heater that uses a refrigeration cycle, such as vapor compression, to transfer heat from a low-temperature source to a higher-temperature sink for the purpose of heating potable water, and has a rated electric power input greater than 12 kW. Such equipment includes, but is not limited to, air-source heat pump water heaters, water-source heat pump water heaters, and direct geo-exchange heat pump water heaters.

Issue 18: DOE requests comment on its proposed definition for "commercial heat pump water heater."

DOE is aware that ANSI/ASHRAE Standard 118.1–2012 ("ASHRAE 118.1–2012"), *Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water-Heating Equipment* is used as an industry test method for CHPWHs. ASHRAE 118.1–2012 includes several test methods, including a method for determining coefficient of performance (COP_h), standby loss for commercial heat pump water heaters, and cooling output of air-source CHPWHs. DOE considered this test procedure for adoption as the Federal test method for CHPWHs. In addition to ASHRAE 118.1–2012, DOE is also aware of another relevant industry standard, the ANSI/AHRI Standard 1300 (I–P)–2013 ("AHRI 1300"), *Performance Rating of Commercial Heat Pump Water Heaters*. AHRI 1300 specifies rating conditions (*e.g.*, entering water temperature, leaving water temperature, and other evaporator side rating conditions) for testing CHPWHs, but it references ASHRAE 118.1–2012 for the actual procedure to conduct the test. DOE considered the rating conditions specified in AHRI 1300 for developing a test procedure for CHPWHs. In the February 2014 RFI, DOE requested public comment on adopting an appropriate test procedure for CHPWHs. DOE sought comment on both of the aforementioned industry test methods and on whether any modifications would be needed for adopting them as the Federal test method. 79 FR 10999, 11003 (Feb. 27, 2014).

DOE received several comments from interested parties in response to this issue. Bradford White supported the use of AHRI 1300 as an appropriate test method for rating CHPWHs. (Bradford White, No. 8 at p. 2) AHRI commented that the efficiency of CHPWHs should be measured at two rating conditions. AHRI also supported the use of AHRI 1300 as the test procedure to measure efficiency of CHPWHs, and HTP stated that it support AHRI's position on this topic. (AHRI, No. 2 at p. 4; HTP, No. 5 at p. 5) Rheem also supported the use of AHRI 1300 as the rating standard. In addition, Rheem supported any modifications to AHRI 1300 that may be required to address issues identified by industry during testing. (Rheem, No. 3 at p. 2) APPA also supported the use of AHRI 1300 for testing CHPWHs and stated that the AHRI 1300 standard references ASHRAE 118.1, which represents an ANSI-approved consensus of multiple stakeholders. (APPA, No. 6 at p. 2) EEI also supported the use of AHRI 1300 for rating CHPWHs. Both APPA and EEI expressed support for the adoption of an industry test procedure to minimize cost by avoiding duplicative testing standards. (APPA, No. 6 at p. 2; EEI, No. 9 at p. 2) A.O. Smith recommended the use of ASHRAE 118.1–2012 and stated that ASHRAE 118.1–2012 is being revised to harmonize its rating conditions with the conditions in AHRI 1300. (A.O. Smith, No. 7 at pp. 2–3)

The Joint Advocates also commented that they strongly support DOE's efforts to adopt a consensus test procedure standard for CHPWHs. To assist DOE in the rulemaking, the Joint Advocates posed several questions that may influence DOE's direction for this rulemaking. The Joint Advocates asked whether there are any international standards that have lessons for U.S. practice. (Joint Advocates, No. 4 at pp. 2–3) DOE reviewed the Collaborative Labeling and Appliance Standards Program's (CLASP's) Global Standards and Labeling Database[18] and determined that no other country has adopted efficiency standards for CHPWHs. Additionally, DOE reviewed the Super-efficient Equipment and Appliance Deployment (SEAD) report on potential for harmonization of international standards for heat pump water heaters.[19] This report primarily discussed residential heat pump water heaters and was not useful in the context of this commercial rulemaking.

The Joint Advocates asked how first-hour supply capability is treated as a capacity measure for CHPWHs. (Joint Advocates, No. 4 at pp. 2–3) DOE acknowledges that delivery capacity of CWH equipment, including CHPWHs, is an important metric for selection and sizing of equipment. However, DOE does not believe such a capacity measure is needed in its test procedure for energy efficiency, as information regarding capacity is already typically readily available in manufacturer literature.

The Joint Advocates asked about the potential impacts of ambient conditions on the test procedure. (Joint Advocates, No. 4 at pp. 2–3) In response, DOE conducted exploratory tests on different CHPWH units at the different rating conditions specified in ASHRAE 118.1–2012 and AHRI 1300. DOE considered the information and results gathered from these tests in the development of the proposed test procedure for CHPWHs. The exploratory tests are discussed in more detail later in this section.

The Joint Advocates raised the issue of the need to consider the capabilities of different refrigerants to achieve temperature rise that is required for commercial applications (*i.e.*, outlet water temperature of ~170 °F). (Joint Advocates, No. 4 at pp. 2–3) DOE notes that most of the CHPWH models available on the market use R–134a, R–410A or R–22 as refrigerants. Further, DOE notes that industry test standards (*e.g.*, ASHRAE 118.1–2012 and AHRI 1300) specify an outlet water temperature of 120 °F for testing of heat pump water heaters, and do not differentiate based on type of refrigerant used. DOE has found in examining CHPWHs, that an outlet water temperature of 120 °F is typical and readily achievable in applications that would be suitable for a CHWPH, regardless of refrigerant type. Based on the foregoing, DOE has tentatively decided not to provide different outlet water temperature conditions based on the type of refrigerant being used.

The Joint Advocates suggested that DOE should consider a different requirement such as maximum rated temperature instead of a constant test temperature. (Joint Advocates, No. 4 at pp. 2–3) DOE's proposed test procedure for CHPWHs includes a provision allowing units that are unable to meet the outlet water temperature at low entering water temperatures to be tested using a higher supply temperature. These provisions are discussed in greater detail later on in this section.

The Joint Advocates asked whether the cooled evaporator air could be used for cooling spaces and whether the energy value of this benefit could be included. (Joint Advocates, No. 4 at pp. 2–3) DOE appreciates that in some sites, cool air rejected from the evaporator coil may provide an ancillary benefit by providing additional space cooling. However, DOE does not propose to include a methodology to measure the cooling performance of a commercial heat pump water heater. DOE finds that such a methodology would be overly burdensome to manufacturers in relation to the uncertain benefit provided to commercial consumers.

In addition, the Joint Advocates expressed their goals for the CHPWH standard as: (1) Allowing fair comparison between products and (2) giving contractors enough information to help customers make informed decisions. According to the Joint Advocates, CHPWHs will require a single metric to be useful and have suggested a blend of the current metrics as a single rating parameter. (Joint Advocates, No. 4 at pp. 2–3) Although DOE proposes a test procedure for CHPWHs in this NOPR, the scope of this rulemaking does not include amending energy conservation standards for CHPWHs. In this NOPR, DOE only proposes a test procedure that manufacturers can use to rate their products, without a requirement to certify COP_h ratings to DOE. In its analysis for this NOPR, DOE considered whether the proposed test procedures for all kinds of CHPWHs would allow for fair comparison between products. Specifically, DOE reviewed and proposes to incorporate by reference certain sections of relevant industry test methods to ensure DOE's test procedure is consistent with industry-accepted test methods. DOE also conducted investigative testing of several air-source CHPWHs from different manufacturers to verify the appropriateness of the proposed test procedure and the consistency of results. With regards to the metric, DOE notes that the industry test standards (ASHRAE 118.1–2012 and AHRI 1300) use the coefficient of performance (COP) as the energy efficiency metric for rating CHPWHs. To ensure consistency with these industry test standards, DOE has tentatively decided to use the same energy efficiency metric (COP) for rating CHPWHs.

The second supplemental comment from AHRI in response to the February 2014 RFI includes recommended rating conditions for testing several kinds of CHPWHs. (AHRI (2015), No. 13, pp. 1–2) AHRI recommended four categories of CHPWHs based on the heat source (*i.e.*, air-source, direct geo-exchange, indoor water-source, and ground water-source) with one set of rating conditions for each category. (AHRI (2015), No. 13 at pp. 1–2) The AHRI-recommended rating conditions that are specified in their comments are shown in Table III–2:

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[18] "CLASP's Global S&L Database." *CLASP* (Dec. 7, 2015) (Available at: *http://www.clasp.ngo/ResourcesTools/Tools/SL_Search*).

[19] Additional information on international standards for HPWHs can be found at: *http://tinyurl.com/jnx79ay.*

TABLE III–2—AHRI-RECOMMENDED CLASSIFICATIONS AND RATING CONDITIONS FOR CHPWHs[20]

Classification based on heat source	Recommended rating conditions
Air-source commercial heat pump water heater	Entering water temperature: 110 °F. Entering air conditions: 80.6 °F dry bulb and 71.2 °F wet bulb.
Direct geo-exchange commercial heat pump water heater	Entering water temperature: 110 °F. Evaporator refrigerant temperature: 32 °F.
Indoor water-source commercial heat pump water heater	Entering water temperature: 110 °F. Evaporator entering water temperature: 68 °F.
Ground water-source commercial heat pump water heater	Entering water temperature: 110 °F. Evaporator entering water temperature: 50 °F.

DOE reviewed AHRI's comments carefully and assessed whether the recommended rating conditions for CHPWHs would sufficiently cover the types of units that are available on the market. As indicated in Table III–2, AHRI recommended separate rating conditions for indoor water-source CHPWHs and ground water-source CHPWHs, despite the fact that both utilize water or another liquid as the evaporator heat source. DOE sees merit in having separate rating conditions for indoor water-source and ground water-source units, because the temperature of water entering the evaporator would be different for each application. However, for the purpose of testing and rating CHPWHs, both indoor water-source CHPWHs and ground water-source CHPWHs can be tested using the same test procedure but with different rating conditions.

ASHRAE 118.1–2012 includes a similar classification with separate test procedures for air-source, direct geo-exchange, and water-source CHPWHs. The test procedure for water-source CHPWHs in ASHRAE 118.1–2012 applies to both indoor water-source CHPWHs and ground water-source CHPWHs. After considering the applications and characteristics of the different kinds of CHPWHs and the classification used in ASHRAE 118.1–2012, DOE proposes separate test procedures for air-source, direct geo-exchange, and water-source CHPWHs. The proposed test procedure for water-source CHPWHs would be used to rate both ground water-source and indoor water-source models with different rating conditions for each category.

To differentiate the four categories of CHPWHs from each other, DOE proposes to add definitions for "Air-source commercial heat pump water heater", "Direct geo-exchange commercial heat pump water heater", "Indoor water-source commercial heat pump water heater", and "Ground water-source commercial heat pump water heater," as set out in the regulatory text at the end of this document.

Issue 19: DOE requests comment on the proposed categories of CHPWHs and related definitions. In particular, DOE requests comments on CHPWH heat sources that are currently available for commercial applications.

To develop new test procedures for all four categories of CHPWHs, DOE reviewed both ASHRAE 118.1–2012 and AHRI 1300. As noted earlier, AHRI 1300 only provides rating conditions and references ASHRAE 118.1–2012 for the actual test method. ASHRAE 118.1–2012 is an industry test method used to rate gas-fired, electric, and oil-fired CWH equipment. For the purpose of testing, ASHRAE 118.1–2012 classifies CHPWHs into two types: (1) "Type IV"—equipment that can be operated without requiring a connection to a storage tank; and (2) "Type V"—equipment that requires connection to a storage tank for operation. ASHRAE 118.1–2012 specifies separate test methods to rate the two types of equipment. The test procedure described in ASHRAE 118.1–2012 for Type V units requires the unit to be connected to a tank that is either supplied by the manufacturer along with the unit or is specified by the manufacturer. However, after reviewing product literature, DOE notes that generally, CHPWH manufacturers neither supply a storage tank with the equipment, nor specify a tank appropriate for that equipment. The ASHRAE 118.1–2012 test procedure does not include a test method for Type V units for which an appropriate tank is neither supplied nor specified by the manufacturer. Without connecting an appropriate tank, Type V equipment cannot be tested using the Type V equipment test procedure as specified in ASHRAE 118.1–2012.

DOE considered establishing a "standard" tank for rating the energy efficiency of Type V units that are not shipped with a tank and for which manufacturers do not specify the tank to be used. However, DOE tentatively determined that testing and rating a CHPWH by connecting it with a separately supplied tank could be an unfair representation of the actual rating of the unit itself since the efficiency of the system is highly dependent on the characteristics of the tank. Further, different CHPWHs may be designed for use with tanks having different characteristics. Theoretically, the combined efficiency rating of a CHPWH unit when operated along with the tank would be lower than the actual rating of that CHPWH unit alone, because the addition of a tank would allow for heat loss through the tank jacket and piping. Also, there may be inconsistencies in selecting tanks used for efficiency testing if manufacturers do not supply or specify an appropriate tank for the CHPWH units. This inconsistency could lead to energy savings smaller than expected for commercial consumers if CHPWHs are tested with storage tanks more efficient than those that those commercial consumers use.

Considering these issues associated with testing a CHPWH unit with an external tank connected to it, DOE explored the possibility of formulating a new test method to test all CHPWH units as Type IV equipment (*i.e.,* without connecting a hot water storage tank while testing). In order to verify the applicability of the Type IV test to all CHPWH units, DOE selected three air-source CHPWH units available on the market and tested them using the test procedure specified in ASHRAE 118.1–2012. DOE tested the units at six different rating conditions specified for air-source CHPWHs by both ASHRAE

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[20] The AHRI recommended classifications and rating conditions for CHPWHs can be found in their comments at: *http://www.regulations.gov/#!documentDetail;D=EERE-2014-BT-TP-0008-0013.*

118.1–2012 and AHRI 1300, as shown in Table III–3. The units that were chosen for testing were purchased from different manufacturers and had varying levels of heating capacities (100,000 Btu/h; 30,000 Btu/h; and 275,000 Btu/h). All of these units had an internal pump fitted within the unit, so no external pump was required to supply inlet water to the condenser of the heat pump.

The test procedure for air-source CHPWHs as specified in ASHRAE 118.1–2012 requires the CHPWH to be set up according to Figure 5 of that test standard. The water flow rate through the unit is adjusted in such a way that the outlet water temperature is maintained at 120 °F ± 5 °F with no variation of more than 2 °F over a three-minute period. DOE conducted the tests under six different rating conditions, which consist of three different evaporator entering air temperatures and two supply water temperature conditions. In all, DOE conducted six tests on each CHPWH unit. These test conditions are shown in Table III–3:

TABLE III–3—RATING CONDITIONS FOR TESTING COMMERCIAL HEAT PUMP WATER HEATERS

Rating conditions	Evaporator entering air temperature [°F]		Condenser entering water temperature [°F]
	Dry bulb	Wet bulb	
1	*95	*75	70
2	80.6	71.2	70
3	50	44.3	70
4	*95	*75	*110
5	80.6	71.2	*110
6	50	44.3	*110

* Rating conditions which are included in ANSI/ASHRAE 118.1–2012. (Note, all rating conditions in this table are included in AHRI 1300–2013.)

The results obtained from these tests indicate that not all the units were capable of achieving an outlet water temperature of 120 °F ± 5 °F. The 30,000 Btu/h unit was the only unit capable of delivering the required outlet water temperature for all six rating conditions. For rating conditions 1, 2, and 3, the flow rate for the 30,000 Btu/h unit had to be sharply reduced to achieve the high temperature rise from a supply water temperature of 70 °F to outlet water temperature of 120 °F ± 5 °F. However, for the rating conditions 4, 5, and 6, the unit successfully delivered water at a temperature of 120 °F ± 5 °F at the manufacturer's specified flow rate.

The 100,000 Btu/h unit was not able to achieve an outlet water temperature of 120 °F ± 5 °F at rating conditions 1 and 2. Moreover, the unit was unable to operate at rating conditions 3 and 6 (evaporator entering air dry bulb temperature of 50 °F) due to low ambient temperature conditions. When the unit was tested at rating conditions 4 and 5, the unit was successful at achieving the 120 °F ± 5 °F outlet water temperature at the manufacturer-rated water flow rate.

The 275,000 Btu/h unit was capable of achieving the required 120 °F ± 5 °F outlet water temperature when tested at rating conditions 1 and 2 with the manufacturer's rated water flow rate. However, the unit did not achieve the required outlet water temperature for any of the other rating conditions. A possible reason for this is the low ambient temperature resulting in lower heat being utilized by the heat pump. For rating conditions 4, 5, and 6 where the supply water temperature is maintained at 110 °F, the outlet water temperature exceeded 120 °F ± 5 °F. The water flow rate for these conditions was at the manufacturer's rated flow rate, and the unit's design did not allow the flow rate to be increased above that value.

Based on these tests, two conclusions can be drawn. First, rating conditions 3 and 6, representing an evaporator entering air dry bulb temperature of 50 °F, were not achievable for two of the tested units, (*i.e.,* the 100,000 Btu/h unit and the 275,000 Btu/h unit). One of the reasons for this is the reduced temperature difference between the refrigerant saturation temperature and the evaporator entering air temperature, which severely limits the evaporator performance. Second, the lower heating capacity units (30,000 Btu/h and 100,000 Btu/h) were able to achieve the required outlet water temperature of 120 °F ± 5 °F at the manufacturer's rated supply water flow rate when the supply water temperature was set to 110 °F, whereas the larger heating capacity unit (275,000 Btu/h) was able to meet the required outlet water temperature condition at the manufacturer's rated flow rate when the supply water temperature was set to 70 °F. This indicates that some units are sized to achieve a low water temperature rise, while others are sized to achieve a higher water temperature rise.

On the basis of these exploratory tests, DOE was able to determine applicability of the test procedure described for "Type IV" units in ASHRAE 118.1–2012 to air-source CHPWH units. Based on the results and the discussion above, DOE has tentatively concluded that the method of test described for "Type IV" units in ASHRAE 118.1–2012 can be used to test air-source CHPWHs but with certain modifications. These proposed modifications include establishing: (1) A single evaporator air entering rating condition with a dry bulb temperature of 80.6 °F ± 1 °F and a wet bulb temperature of 71.2 °F ± 1 °F; (2) a supply water temperature of 70 °F ± 1 °F (or 110 °F ± 1 °F, only if the required outlet water temperature condition is not achieved while testing at a supply water temperature of 70 °F ± 1 °F).

DOE did not conduct exploratory tests for other categories of CHPWHs (*i.e.,* direct geo-exchange, indoor water-source, and ground water-source CHPWHs). As discussed previously, AHRI's initial comment recommended using AHRI 1300 for rating CHPWHs (which utilizes ASHRAE 118.1–2012 as the actual procedure), and AHRI's supplemental comment suggested rating conditions appropriate for direct geo-exchange, indoor water-source, and ground water-source CHPWHs. As DOE has not identified any other industry test method applicable to CHPWHs, DOE has tentatively determined to use the test method for "Type IV" equipment specified in ASHRAE 118.1–2012 with rating conditions recommended by AHRI (Table III–2) for testing the energy efficiency of direct geo-exchange, indoor water-source, and ground water-source CHPWHs. Specifically, DOE proposes that direct geo-exchange CHPWHs be tested using the ASHRAE 118.1–2012 test procedure for "Type IV" direct geo-exchange heat pump water heaters with an entering water temperature of 110 °F and evaporator refrigerant temperature of 32 °F. DOE proposes indoor water-source and ground water-source CHPWHs be tested according to the ASHRAE 118.1–2012 test procedure for "Type IV" water-source heat pump water heaters, with an entering water temperature of 110 °F and evaporator entering water temperature of 68 °F and 50 °F for indoor water-source and ground water-source CHPWHs, respectively.

ASHRAE 118.1–2012 provides several test procedure metrics for measuring energy efficiency (*e.g.,* Coefficient of performance with full input rating (section 9.1.1 of ASHRAE 118.1), Coefficient of performance with reduced input rating (9.1.2 of ASHRAE 118.1), standby energy consumption (section 9.2 of ASHRAE 118.1), and cooling output (section 9.3 of ASHRAE 118.1)). Coefficient of performance refers to the ratio of the useful heat gained by the water (in Btu/h) to the electric power consumed by the unit (in Btu/h). For the current rulemaking, DOE proposes to use the test procedure for measuring coefficient of performance for full input rating. DOE also proposes to define "coefficient of performance" as set out in the regulatory text at the end of this document.

As previously noted, DOE's proposed test procedure for rating CHPWHs would incorporate by reference certain relevant sections of ASHRAE 118.1–2012. The succeeding paragraphs highlight various sections that are relevant to testing units of all four categories of CHPWHs.

DOE proposes that the instrumentation required for the new test procedure would be as described in section 6 of ASHRAE 118.1. Further, DOE proposes that the test set-up, piping, and temperature-sensing locations be as described in sections 7.1, 7.2.1, 7.3.2, 7.3.3, 7.5, and 7.6 of that industry standard for testing Type IV equipment. DOE also proposes to incorporate subsections 7.7.1 to 7.7.6 with the exclusion of section 7.7.5 of ASHRAE 118.1–2012. Section 7.7.5 of ASHRAE 118.1–2012 contains special requirements for testing a heat pump water heater for measurement of space cooling. Section 7.7.7 of ASHRAE 118.1–2012 refers to Table 2 of the same test standard, which provides values for supply (or entering) water temperatures for testing CHPWHs. DOE has tentatively decided not to directly adopt section 7.7.7 of ASHRAE 118.1–2012 and instead proposes to adopt the following provisions to replace section 7.7.7 as follows:

Modifications for Water-Source CHPWHs and Direct Geo-Exchange CHPWHs

DOE proposes to test direct geo-exchange, indoor water-source, and ground water-source CHPWHs with a nominal entering water temperature of 110 °F instead of the temperature specified in Table 2 referenced by section 7.7.7 of ASHRAE 118.1.

Modifications for Air-Source CHPWHs

DOE proposes that air-source CHPWH equipment be tested with a supply water temperature of 70 °F ± 1 °F. If the required outlet water temperature condition (specified in section 8.7.2 of ASHRAE 118.1–2012) is not met while testing the unit at 70 °F ± 1 °F, only then should the supply water temperature be provided at 110 °F ± 1 °F. DOE proposes to use the following steps for setting the supply water temperature that would be applicable to the air-source CHPWH unit being tested:

(1) Set the supply water temperature at 70 °F ± 1 °F and the water flow rate to the rated pump flow rate and start operating the unit. Measure the outlet water temperature at this flow rate to check if an outlet water temperature of 120 °F ± 5 °F is achieved as specified in section 8.7.2 of ASHRAE 118.1–2012. If the outlet water temperature is maintained at this condition (*i.e.,* at a temperature of 120 °F ± 5 °F and with no variation of more than 2 °F over a three-minute period), then conduct the test as per section 9.1.1 of ASHRAE 118.1–2012.

(2) If the outlet water temperature condition is not met, then adjust the flow rate in order to meet the required outlet water temperature condition as per section 8.7.2 of ASHRAE 118.1–2012. Measure the outlet water temperature at the adjusted flow rate to check if an outlet water temperature of 120 °F ± 5 °F is achieved as specified in section 8.7.2 of ASHRAE 118.1–2012. If the outlet water temperature is maintained at this condition (*i.e.,* at a temperature of 120 °F ± 5 °F and with no variation of more than 2 °F over a three-minute period), then conduct the test as per section 9.1.1 of ASHRAE 118.1–2012.

(3) If, after adjusting the flow rate within the range that is achievable by the pump, the equipment is unable to operate or deliver the required outlet water temperature, then reset the flow rate to the rated pump flow rate and change the supply water temperature to 110 °F ± 1 °F. Measure the outlet water temperature at the rated pump flow rate to determine whether the outlet water temperature requirement is met as per section 8.7.2 of ASHRAE 118.1–2012. If the outlet water temperature is maintained at this condition (*i.e.,* at a temperature of 120 °F ± 5 °F and with no variation of more than 2 °F over a three-minute period), then conduct the test as per section 9.1.1 of ASHRAE 118.1–2012.

(4) If the outlet water temperature condition is not met, then adjust the flow rate in order to meet the required outlet water condition as per section 8.7.2 of ASHRAE 118.1–2012. Measure the outlet water temperature at the adjusted flow rate to check if an outlet water temperature of 110 °F ± 1 °F is achieved as specified in section 8.7.2 of ASHRAE 118.1–2012. If the outlet water temperature is maintained at this condition (*i.e.,* at a temperature of 120 °F ± 5 °F and with no variation of more than 2 °F over a three-minute period), then conduct the test as per section 9.1.1 of ASHRAE 118.1–2012.

(5) If the outlet water temperature condition cannot be met, then a test procedure waiver is necessary to specify an alternative set of test conditions.

DOE proposes to retain Table 3 of ASHRAE 118.1–2012, which provides tolerances of different parameters (*e.g.,* water temperatures, water flow rates) and, sections 7.7.7.1 and 7.7.7.2 of ASHRAE 118.1–2012 that specifies requirements for measurement of water flow and temperature. If the CHPWH is equipped with a thermostat that controls the throttling valve, then use section 7.7.7.3 of ASHRAE 118.1–2012 to set up the thermostat. DOE also proposes to use sections 8.2.1 and 8.7.2 of ASHRAE 118.1–2012 for specifying electrical supply and outlet water temperature requirements, respectively. The method of test would be as per the test procedure specified in section 9.1.1 of ASHRAE 118.1. The rating conditions in ASHRAE 118.1–2012 are contained tables B–1, B–2, and B–3 of appendix B5 of the industry test standard, and referenced from section 9.4.1 of that test method. Rather than use the rating conditions specified in ASHRAE 118.1–2012, DOE proposes to use a single rating condition for each category of CHPWHs as specified in Table III–4:

TABLE III–4—PROPOSED RATING CONDITIONS FOR CHPWHS

Category of CHPWH	Evaporator side rating conditions	Condenser side rating conditions
Air-source commercial heat pump water heater	Evaporator entering air conditions: Dry bulb: 80.6 °F ± 1 °F and Wet bulb: 71.2 °F ± 1 °F	Entering water temperature: 70 °F ± 1 °F. Vary water flow rate (if needed) to achieve the outlet water temperature as specified in section 8.7.2 of ASHRAE 118.1–2012. If required outlet water temperature as specified in section 8.7.2 of ASHRAE 118.1–2012 is not met even after varying the flow rate, then change the condenser entering water temperature to 110 °F ± 1 °F. Vary flow rate to achieve the conditions in section 8.7.2 of ASHRAE 118.1–2012.
Direct geo-exchange commercial heat pump water heater.	Evaporator refrigerant temperature: 32 °F ± 1 °F.	Entering water temperature: 110 °F ± 1 °F.
Indoor water-source commercial heat pump water heater.	Evaporator entering water temperature: 68 °F ± 1 °F.	Entering water temperature: 110 °F ± 1 °F.
Ground water-source commercial heat pump water heater.	Evaporator entering water temperature: 50 °F ± 1 °F.	Entering water temperature: 110 °F ± 1 °F.

To calculate the final COP_h value, DOE proposes to use section 10.3.1 of ASHRAE 118.1–2012.

To further assess the new test method, DOE conducted a second round of experimental testing on the 100,000 Btu/h CHPWH unit. In this round, the test was carried out exactly as per the proposed test procedure specified in appendix F to subpart G of part 431 and proposed in this section of the NOPR. DOE tested the unit with evaporator entering air temperatures specified in appendix F to subpart G of part 431 (also specified in Table III–4). As proposed, the unit was first tested with a supply water temperature of 70 °F ± 1 °F. At these rating conditions, the unit was unable to achieve an outlet water temperature of 120 °F ± 5 °F, even after varying the supply water flow rate. The supply water temperature was then re-adjusted to 110 °F ± 1 °F. At this temperature, the unit was successful in delivering and maintaining an outlet water temperature of 120 °F ± 5 °F with no variation of more than 2 °F over a three-minute duration. Results show that the COP_h value obtained in the second round of testing in reasonably close agreement between the COP_h measured in the first round of testing, indicative of the repeatability and practicability of the proposed test procedure.

Issue 20: DOE requests comment on all aspects of the proposed test procedure for commercial heat pump water heaters, and in particular, the proposal to test all units without a storage tank. DOE also invites comment on its recommended rating conditions, particularly the supply water temperatures for air-source commercial heat pump water heaters.

K. Fuel Input Rate

In DOE's existing regulations, equipment classes and the standards that apply to them are determined partly on the basis of the input capacity of the CWH equipment. However, several terms are used in the existing DOE test procedures and energy conservation standards to describe the capacity of the CWH equipment, each of which is derived from the maximum rated fuel input rate to the CWH equipment. For example, the existing DOE test procedure for CWH equipment at 10 CFR 431.106 uses the term "hourly Btu input rate" to describe the measured input rate during the test and "manufacturer's specified input rate" as the value to which the measured input rate should be compared. The energy conservation standards for CWH equipment at 10 CFR 431.110 use the term "nameplate input rate," which is intended to mean the same thing as "manufacturer's specified input rate." While DOE's test procedure for oil-fired CWH equipment requires the hourly Btu input rate to be within ±2 percent of the manufacturer's specified input rate, no procedure is included for measuring the input rate.

To clarify standardize terminology throughout its regulations for CWH equipment and to determine the appropriate equipment class for CWH equipment, DOE proposes to define the term "fuel input rate" as set out in the regulatory text at the end of this document.

DOE proposes to use this term in the division of equipment classes and applicable testing provisions to determine the fuel input rate. Manufacturers would be required to measure the fuel input rate during certification testing and use the mean of the measured values, after applying the applicable rounding provisions (discussed later in this section), in certification reports pursuant to 10 CFR 429.44(c)(2). DOE also notes that, for CWH equipment certified using an AEDM, the AEDM would be used to determine the fuel input rate and the same rounding provisions would apply. DOE believes it is critical to clarify how the fuel input rate is to be determined because the applicable standards for certain classes of CWH equipment are based in part on the fuel input rate. These proposed additions would clarify for manufacturers what energy conservation standard applies to a given basic model.

DOE also proposes to include equations for determination of fuel input rate in its test procedures for gas-fired and oil-fired CWH equipment. DOE proposes to include Equations C2 and C3 from section C7.2.3 of AHRI 1500–2015 in its test procedures for calculation of fuel input rate for gas-fired and oil-fired CWH equipment, respectively. DOE also proposes that the fuel input rate be determined by measuring fuel consumption at 3 consecutive 10-minute intervals during the 30-minute thermal efficiency test. The overall fuel input rate for the thermal efficiency test will be calculated using the fuel consumption over the entire 30-minute test. DOE proposes that during the thermal efficiency test, the measured fuel input rate must not vary by more than ±2 percent between 10-minute interval readings.

Section 5.2.2 of AHRI 1500–2015 specifies rounding gross output (as defined in section 3.20 of AHRI 1500–2015) to the nearest 1,000 Btu/h. However, DOE regulations are based on input rate, not gross output. Therefore, DOE proposes adding a requirement to the DOE test procedure that values of fuel input rate for each unit tested be rounded to the nearest 1,000 Btu/h.

Additionally, DOE proposes that, for its enforcement testing, the overall fuel input rate for the thermal efficiency test would be measured pursuant to 10 CFR 431.106 and compared against the fuel input rate certified by the manufacturer. If the measured fuel input rate is within ±2 percent of the certified value, then DOE will use the certified value when determining which equipment class to regulate a model. If the measured fuel input rate is not within ±2 percent of the certified value, then DOE will attempt the following steps to bring the fuel input rate to within ±2 percent of the certified value. First, DOE will attempt to adjust the gas pressure in order to increase or decrease the fuel input rate within the gas pressure range allowed by the test procedure. If the fuel input rate is still not within ±2 percent of the certified value, DOE will then attempt to modify the gas inlet orifice (*e.g.* drill) accordingly. Finally, if these measures do not bring the fuel input rate to within ±2 percent of the certified value, DOE will use the measured fuel input rate when determining the equipment class. DOE proposes a fuel input rate tolerance of ±2 percent based on the steady-state criteria included in sections C4.1.1.1.4 and C4.1.2.1.5 of AHRI 1500–2015, and has tentatively concluded that such a requirement would not impose additional testing burden or affect ratings. DOE proposes this verification process to provide manufacturers with additional information about how DOE will evaluate compliance.

Issue 21: DOE seeks comment regarding its proposed definition and methodology for measuring and verifying fuel input rate for gas-fired and oil-fired CWH equipment.

L. Default Values for Certain Test Parameters for Commercial Water Heating Equipment

DOE incorporates by reference Exhibits G.1 and G.2 of ANSI Z21.10.3–2011 (which correspond to Annexes E.1 and E.2 of ANSI Z21.10.3–2015) in its current test procedure for thermal efficiency and standby loss for CWH equipment. Some of the equipment settings for performing the test procedures as per Annex E.1 of ANSI Z21.10.3–2015 (*e.g.,* water supply pressure, venting requirements) are required to be specified by manufacturers. DOE proposes to include default values for these parameters in its test procedures, to be used if values are not specified in manufacturer literature shipped with the unit[21] or supplemental test information. Specifically, if these values are not included in manufacturer literature shipped with the unit, then DOE will use the values included in the supplemental testing instructions if one is submitted with the certification report. If the values are neither included in manufacturer literature shipped with the unit or in the supplemental test instructions, then DOE will use the default values proposed in this NOPR. These test procedures and default values would apply to commercial water heating equipment other than residential-duty commercial water heaters.

For all commercial water heating equipment, DOE proposes a default value for maximum water supply pressure of 150 pounds per square inch (psi). For gas-fired commercial water heating equipment powered with natural gas, DOE proposes a default range of allowable gas supply pressure of 4.5 inches of water column (in. w.c.) to 10.5 in. w.c. For gas-fired commercial water heating equipment powered with propane, DOE proposes a default range of 11 in. w.c. to 13 in. w.c.

DOE also includes several requirements specific to oil-fired equipment in its current test procedure for commercial water heating equipment as set forth in 10 CFR 431.106. These requirements include:

(1) Venting Requirements—Connect a vertical length of flue pipe to the flue gas outlet of sufficient height so as to meet the minimum draft specified by the manufacturer; and (2) Oil Supply—Adjust the burner rate so that: (a) The hourly Btu input rate lies within ±2 percent of the manufacturer's specified input rate, (b) the CO_2 reading shows the value specified by the manufacturer, (c) smoke in the flue does not exceed No. 1 smoke as measured by the procedure in ASTM–D–2156–80, and (d) fuel pump pressure lies within ±10 percent of manufacturer's specifications.

These requirements depend on manufacturer specifications, including the minimum draft, input rate, CO_2 reading, and fuel pump pressure. Manufacturers are already required to certify the input rate of all covered oil-fired equipment in certification reports submitted to DOE for each basic model. However, not all manufacturers describe venting guidelines for their units using the same format and parameters, and DOE does not wish to establish default values that contradict manufacturer specifications. Therefore, DOE proposes to include a default value for fuel pump pressure and a default range for CO_2 reading in its test procedures, which would only be used if the parameters are not specified in the manufacturer's literature shipped with the unit or in the supplemental test instructions. DOE proposes default values of an allowable range of 9–12 percent for CO_2 reading, and 100 psig fuel pump pressure. DOE determined these values from examination of values for units currently on the market.

Issue 22: DOE requests comment on its proposed default values for maximum water supply pressure for all equipment, allowable gas supply pressure range for equipment powered with natural gas and propane, and the CO_2 reading and fuel pump pressure for oil-fired equipment.

M. Certification Requirements

DOE proposes several changes to its certification requirements for commercial water heating equipment[22] at 10 CFR part 429. DOE proposes to add two requirements to 10 CFR 429.44 for certification of instantaneous water heaters and hot water supply boilers. First, DOE proposes to add that manufacturers must certify whether instantaneous water heaters or hot water supply boilers contain submerged heat exchangers or heating elements, in order to allow for proper classification of units under DOE's proposed definition for "storage-type instantaneous water heater." DOE's classification for storage-type instantaneous water heaters is discussed in more detail in section III.F. Second, DOE proposes to add that manufacturers must certify whether instantaneous water heaters or hot water supply boilers require flow of water through the water heater to initiate burner ignition.

Issue 23: DOE requests comment on its proposed additional certification requirements for instantaneous water heaters and hot water supply boilers, and seeks feedback on any other information that should be included for any classes of CWH equipment.

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[21] Manufacturer literature includes any information on settings, installation, and operation that is shipped with the equipment. This information can be in the form of installation and operation manuals, settings provided on a name plate, or product-specific literature.

[22] DOE is also making an editorial change to the certification report provisions in 10 CFR 429.44(c) for commercial water heating equipment by replacing of the term "water heater" and abbreviations of water heater (*i.e.,* WH) with the term "water heating."

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866

The Office of Management and Budget (OMB) has determined that test procedure rulemakings do not constitute "significant regulatory actions" under section 3(f) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993). Accordingly, this regulatory action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment and a final regulatory flexibility analysis (FRFA) for any such rule that an agency adopts as a final rule, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. A regulatory flexibility analysis examines the impact of the rule on small entities and considers alternative ways of reducing negative effects. Also, as required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site at: *http://energy.gov/gc/office-general-counsel.*

This proposed rule would prescribe test procedure amendments that would be used to determine compliance with energy conservation standards for CWH equipment (except for CHPWHs). The proposed amendments would: (1) Update the referenced industry test standards by incorporating by reference ASTM D2156–09, ASTM C177–13, ASTM C518–10, and Annex E.1 of ANSI Z21.10.3–2015; (2) modify the thermal efficiency and standby loss tests for CWH equipment to improve repeatability; (3) include an updated test method for determining the efficiency of unfired hot water storage tanks; (4) change the method for setting the thermostat in the thermal efficiency test for gas-fired and oil-fired storage water heaters and storage-type instantaneous water heaters from measurement of mean tank temperature to measurement of outlet water temperature; (5) clarify test conditions required in the thermal efficiency test method with regard to stored energy loss and steady-state operation; (6) define "storage-type instantaneous water heater" and modify several definitions for consumer water heaters and commercial water heating equipment included at 10 CFR 430.2 and 10 CFR 431.102, respectively; (7) include a new test method for measurement of standby loss for flow-activated instantaneous water heaters; (8) specify temperature-sensing locations, water valve locations and clarifications for using a recirculating loop for thermal efficiency and standby loss testing of instantaneous water heaters and hot water supply boilers; (9) replace the measurement of mean tank temperature with outlet water temperature for thermostatically-activated instantaneous water heaters (other than storage-type instantaneous water heaters); (10) include a new test method for rating commercial heat pump water heaters; (11) establish a procedure for determining the fuel input rate of gas-fired and oil-fired CWH equipment and specify DOE's measures to verify fuel input rate; (12) add default values for certain testing parameters for commercial water heating equipment; and (13) modify DOE's certification requirements for commercial water heating equipment. DOE reviewed all of these proposed amendments to the existing test procedure under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. 68 FR 7990. Accordingly, DOE has prepared the following IRFA for the equipment that is the subject of this rulemaking.

1. Description and Estimated Number of Small Entities to Which the Proposed Rule Would Apply

For manufacturers of covered CWH equipment, the Small Business Administration (SBA) has set a size threshold, which defines those entities classified as "small businesses" for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. 65 FR 30836, 30848 (May 15, 2000), as amended at 77 FR 49991, 50000, 50011 (August 20, 2012) and codified at 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at: *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.* Manufacturing of CWH equipment is classified under NAICS 333318, "Other Commercial and Service Industry Machinery Manufacturing."[23] The SBA sets a size threshold of 1,000 employees or fewer for a manufacturer that falls under this category to qualify as a small business.

To estimate the number of companies that could be small business manufacturers of equipment covered by this rulemaking, DOE conducted market research and created a database of CWH equipment manufacturers that identified the manufacturers which qualify as small businesses among that list. DOE's research involved industry trade association membership directories (including AHRI[24]), public databases (*e.g.*, the California Energy Commission Appliance Efficiency Database[25]), individual company Web sites, and market research tools (*e.g.*, Hoovers reports[26]) to create a list of companies that manufacture or sell equipment covered by this rulemaking. DOE's research resulted in a list of all domestic small business manufacturers of CWH equipment covered by this rulemaking. DOE also contacted companies, as necessary, to determine if they both meet the SBA's definition of a "small business" manufacturer and have their manufacturing facilities located within the United States. DOE screened out companies that did not offer products covered by this rulemaking, did not meet the definition of a "small business," or a foreign-owned and operated. Based upon this analysis and comprehensive search, DOE identified 28 manufacturers of CWH equipment affected by changes proposed in this NOPR. Of these 28, DOE identified 16 as domestic small businesses. Fifteen of the 16 domestic small businesses are original equipment manufacturers (OEMs) of CWH equipment covered by this rulemaking, while one rebrands equipment manufactured by other OEMs. These fifteen small businesses represent approximately 54 percent of domestic companies that manufacture CWH equipment affected by changes proposed in this NOPR.

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[23] On October 1, 2012, the NAICS code for "Other Commercial and Service Industry Machinery Manufacturing," which includes manufacturing of commercial water heating equipment, changed from 333319 to 333318.

[24] The AHRI Directory is available at: *www.ahridirectory.org/ahriDirectory/pages/home.aspx.*

[25] The CEC database is available at: *http://www.energy.ca.gov/appliances/.*

[26] Hoovers Inc., Company Profiles, Various Companies (Available at: *www.hoovers.com/*).

2. Description and Estimate of Compliance Requirements

In the following sections, DOE discusses the potential burdens that could be faced by manufacturers of CWH equipment, particularly small businesses, as a result of each of the test procedure amendments proposed in this NOPR.

Updated Industry Test Methods

The proposal to update the currently-referenced industry test method edition from ANSI Z21.10.3–2011 (Exhibits G.1 and G.2) to ANSI Z21.10.3–2015 (Annex E.1) would not impact the requirements, conditions, or duration of DOE's test procedures. DOE only identified one substantive difference between the efficiency test methods in each version—the standby loss equation. Because DOE tentatively concluded that the equation in the currently referenced ANSI Z21.10.3–2011 is correct and proposes to retain that equation in its test procedures, this updated reference to the industry test method should not affect conduct of or ratings from DOE's test procedure.

DOE's current test procedure, specified at 10 CFR 431.106, also requires that flue gases from oil-fired CWH equipment not contain smoke that exceeds No. 1 smoke, as determined by ASTM Standard D2156–80. In this NOPR, DOE proposed to update this reference and incorporate by reference the most recent version of this test method, ASTM D2156–09. DOE did not identify any significant differences between the two versions of this test method; therefore, DOE has tentatively concluded that this updated reference should not affect results from its test procedure. Additionally, DOE proposes several clarifications to the procedure for determining smoke spot number. First, DOE proposes to clarify that the smoke spot number is to be determined once steady-state operation is achieved but before beginning measurements for the thermal efficiency test. Second, DOE proposes to require that the smoke measuring device be connected to an open-ended tube that projects into the flue ¼ to ½ of the pipe diameter. This requirement for the smoke measuring device is adopted from those specified for commercial space heating boilers in AHRI 1500–2015. DOE also proposes to clarify that the smoke spot test is required before conduct of the thermal efficiency test or standby loss test (as applicable) of oil-fired CWH equipment. However, DOE proposes not to require the smoke spot test be conducted prior to beginning an efficiency test (*i.e.*, thermal efficiency or standby loss) if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test. DOE also proposes that the CO_2 reading be measured at the same times that are required for determining the smoke spot number.

DOE proposes clarification of the test procedure for determining smoke spot number because the current procedure as specified in 10 CFR 431.106 does not specify the timing or location of measuring the smoke spot number. DOE considers conduct of the smoke spot test and measurement of CO_2 reading before the thermal efficiency test begins to be a less burdensome method than measuring during the test, and, therefore, does not consider this clarification likely to increase testing burden to manufacturers. Additionally, DOE considers its clarification regarding when the smoke spot test and measurement of CO_2 reading are not needed (*i.e.*, when the standby loss test is conducted after the thermal efficiency test) to reduce burden compared to a requirement to measure before the standby loss test or compared to the current test procedure, which simply states that the flue cannot exceed No. 1 smoke. Finally, DOE considers its proposed specification of the location within the flue for determination of smoke spot number unlikely to increase burden to manufacturers, given that this requirement was adopted from an industry-accepted test method for similar commercial HVAC equipment.

DOE's current definition for "R-value" at 10 CFR 431.102 references two industry test methods, ASTM C177–97 and ASTM C518–91. In this NOPR, DOE proposes to incorporate by reference the most recent versions of these test methods: ASTM C177–13 and ASTM C518–10. DOE did not identify any significant differences in the procedures for measuring R-value between the two versions of ASTM C177 or between the two versions of ASTM C518. Therefore, this updated reference should not affect results for calculation of R-value per DOE's definition at 10 CFR 431.102.

Test Procedure Repeatability and Ambient Conditions

The proposed modifications to the thermal efficiency and standby loss test methods include: (1) Stipulating a maximum air draft requirement of 50 ft/min as measured prior to beginning the thermal efficiency or standby loss tests; (2) tightening the ambient room temperature tolerance from ±10.0 °F to ±5.0 °F and the allowed variance from mean ambient temperature from ±7.0 °F to ±2.0 °F; (3) requiring measurement of test air temperature—the temperature of entering combustion air—and requiring the test air temperature not vary by more than ±5 °F from the ambient room temperature at any measurement interval during the thermal efficiency and standby loss tests for gas-fired and oil-fired CWH equipment; (4) establishing a requirement for ambient relative humidity of 60 percent ±5 percent during the thermal efficiency and standby loss tests for gas-fired and oil-fired CWH equipment; (5) requiring a soak-in period prior to testing in which the water heater must sit without any draws taking place for at least 12 hours from the end of a recovery from a cold start; (6) specifying the locations of inlet and outlet temperature measurements for storage water heaters, storage-type instantaneous water heaters, and UFHWSTs; and (7) decreasing the time interval for data collection from fifteen minutes to 30 seconds in the thermal efficiency and standby loss tests.

For the first modification, depending on the conditions in the manufacturer's testing area, the manufacturer may need to protect the testing area from drafts greater than 50 ft/min. This draft protection could be accomplished by using wind barriers such as moveable walls, minimizing the opening and closing of doors near the test stand, or sealing windows. To measure draft velocity, manufacturers may have to purchase instrumentation that DOE estimates could cost up to $250. However, any manufacturer of residential water heaters should already have this instrumentation and be able to comply with this stipulation, because it is similar to the requirement established for testing residential water heaters in the July 2014 final rule. 79 FR 40542, 40569 (July 11, 2014).

For the second, third, and fourth modifications that propose changes to specified ambient conditions, manufacturers may not need to make any changes if the ambient temperature and relative humidity in their testing area already meet the proposed tolerances. DOE is aware that the proposed constraints may in some cases require laboratories to move testing from an uncontrolled environment (*i.e.*, outdoors or facilities open to the outdoors) to a controlled environment. However, DOE understands this to be a small number of cases, and that testing is routinely performed in a laboratory setting with typical heating, ventilating, and air-conditioning systems and controls. DOE notes that the limits are intended to prevent the test from being conducted in extreme ambient conditions, and that the ambient temperature requirements are typical for building heating, ventilating, and air-conditioning systems in normal operating condition. However, if the ambient temperature or relative humidity in the testing area do not already meet these tolerances, the manufacturer may need to improve climate regulation of the test environment, possibly by improving the controls of their thermostats, or preventing hot or cold drafts from entering the testing environment. DOE estimates that improving the controls of the thermostat and preventing hot or cold drafts from entering the testing environment could involve four to eight hours of labor by a general technician. At a rate of $40 per hour for a laboratory technician, DOE estimates the cost for this amount of labor to be between $160 and $320, which DOE believes is modest in comparison to the overall cost of product development and certification.[27]

For the third modification, manufacturers need to measure the test air temperature, which is measured within two feet of the combustion air inlet. While this requirement was adopted from an industry test method for commercial packaged boilers, AHRI 1500–2015, it is not currently required for testing of CWH equipment. Therefore, manufacturers would need to install temperature measuring devices in close proximity to the air intake. However, DOE believes that a requirement for this temperature measurement would not present any significant testing burden to manufacturers, because it would simply involve one more temperature measurement than is already being conducted, and the temperature readings could be recorded using the same data acquisition software that is used for measuring the ambient room temperature.

The fifth modification specifies a 12-hour pre-conditioning period prior to conducting the standby loss test for storage water heaters and storage-type instantaneous water heaters. While this would add to the time required to conduct the test, it would not require extra personnel and would not necessitate the development of additional test platforms. DOE understands that a preconditioning period is already implemented by manufacturers as a best practice to allow the water heater to achieve operational temperature, so the added burden from the 12-hour soak-in would be minimal. In addition, these tests can be conducted in the same facilities used for the current energy testing of these products, so there would be no additional facility costs required by this proposal.

The sixth modification specifies the location for measurement of inlet and outlet temperature for storage water heaters, storage-type instantaneous water heaters, and UFHWSTs. DOE expects these lengths to align with the piping set-ups currently used in most testing of CWH equipment. If slight modifications would be needed to the set-ups currently used, DOE believes that these modifications would be simple and merely involve adding or removing several inches of piping. Additionally, DOE proposes set-ups for tanks water heaters and storage tanks with connections on the top, side, or bottom—thereby minimizing the likelihood that a significant change to the set-up currently used by manufacturers would be needed. Therefore, DOE has tentatively concluded that this aspect of its proposal would not present a significant burden to manufacturers, including small businesses.

Finally, DOE proposes reducing the time interval for data collection during the thermal efficiency test from 1 minute to 30 seconds and during the standby loss test from 15 minutes to 30 seconds. Because manufacturers are already required to measure at one-minute intervals for the current thermal efficiency test, DOE reasons that manufacturers already use a computer-connected data acquisition system. Changing the time intervals for recording measurements on a data acquisition system is a quick process that requires the operator to simply change the parameters on the computer using the data acquisition system software. Therefore, the manufacturers would not incur any additional testing costs due to the proposed changes in the data recording time intervals.

Unfired Hot Water Storage Tanks

DOE also proposes to adopt a new metric and test procedure for testing the efficiency of unfired hot water storage tanks. In order to comply with Federal regulations, unfired hot water storage tanks are currently required to meet a minimum thermal insulation R-value of 12.5 $\cdot$°F$\cdot$ft^2$\cdot$h/Btu. In this NOPR, DOE proposes to adopt a new standby loss metric determined by a new standby loss test method for this class. If this test procedure is adopted, certification of standby loss for covered unfired hot water storage tanks would not be required unless and until DOE establishes energy conservation standards in terms of standby loss for this class. However, DOE acknowledges that absent a standby loss standard, some manufacturers may choose to rate the efficiency of their unfired hot water storage tank models to help distinguish their products from competitor offerings.

Manufacturers likely already have all necessary equipment and instrumentation for the proposed test method for unfired hot water storage tanks, because such equipment and instrumentation are already needed for testing of other CWH equipment classes. Through its review of the market, DOE found that all unfired hot water storage tank manufacturers also produce other covered CWH equipment, such as storage water heaters, instantaneous water heaters, or hot water supply boilers. Therefore, DOE has tentatively concluded that manufacturers would not incur any additional test facility costs. Small manufacturers with a small number of UFHWST offerings could choose to conduct testing with a third-party lab, which DOE estimates would cost no more than $3,000 per tested UFHWST.

DOE estimates that testing of each unfired hot water storage tank would take less than 2 days, including set-up and testing of storage volume and standby loss. However, the majority of this time would not require attendance by any employees. DOE estimates that setting up and removing the unfired hot water storage tanks from the test stand might require 2–3 hours of time from a laboratory technician. At a rate of $40 per hour for a laboratory technician, DOE estimates the cost for this amount of labor to be no more than $80–$120. Additionally, DOE estimates it would take approximately 1 hour of a lab technician's time to complete the test procedure per model tested, which would result in a cost of $40. Therefore, the total labor cost of testing an unfired hot water storage tank would be $120–$160 per model.

Issue 24: DOE requests comment on its cost estimates for manufacturers to test their unfired hot water storage tanks according to DOE's proposed test method.

Thermostat Settings

DOE proposes to change the measurement of temperature in the thermal efficiency test by measuring the outlet water temperature rather than the mean tank temperature for gas-fired and oil-fired storage water heaters and storage-type instantaneous water heaters. This proposal was suggested by manufacturers so that their models can more easily meet the specified conditions in the test procedure without having to sacrifice thermal efficiency gains when designing equipment. Because the outlet water temperature is already measured in the current test method, this proposal would simplify DOE's test procedure, and would not create any additional test burden for manufacturers, including small businesses.

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[27] Based on mean hourly wage from Bureau of Labor Statistics for Mechanical Engineering Technician, occupational code 17–3027: *http://www.bls.gov/oes/current/oes173027.htm.* Mean hourly wage is multiplied by 1.5 to estimate associated benefits and overhead.

Clarifications to the Thermal Efficiency and Standby Loss Test Procedures

DOE proposes to add clarifying statements to its thermal efficiency and standby loss test procedures. Specifically, DOE proposes to clarify that that during the thermal efficiency test, the burner must continuously fire at the full firing rate for the entire duration of the test and that the outlet water temperature must be maintained at 70 °F ± 2 °F above the supply water temperature. DOE also proposes to clarify that during the thermal efficiency and standby loss tests, no settings on the water heating equipment can be changed until measurements for the test have finished. As discussed in section III.E, several manufacturers indicated that there was not a problem with the current test procedure, as there is a general understanding that the burner must fire at its full input rate throughout the course of the test. Additionally, DOE expects that the majority of manufacturers already perform the thermal efficiency and standby loss tests in a manner as clarified in DOE's proposal. Therefore, DOE has tentatively concluded that its proposed clarifying statements would only serve to remove any potential confusion regarding its test procedures, and would not add any burden to manufacturers, including small businesses.

Storage-Type Instantaneous Water Heaters

DOE proposes a new definition for "storage-type instantaneous water heater," which are instantaneous water heaters with integral storage tanks and a submerged heat exchanger(s) or heating element(s). DOE believes this kind of water heater should be tested similar to storage water heaters. However, DOE does not currently prescribe separate test procedures for storage water heaters and instantaneous water heaters. Only in the test procedures proposed in this NOPR does DOE prescribe separate standby loss test methods for storage water heaters and instantaneous water heaters. Additionally, DOE's research suggests that manufacturers already categorize units falling under DOE's proposed definition for "storage-type instantaneous water heater" with storage water heaters. Therefore, DOE has tentatively concluded that applying the test procedure prescribed for storage water heaters to storage-type instantaneous water heaters would not present a burden for manufacturers, including small businesses.

Flow-Activated Instantaneous Water Heaters

Currently, all instantaneous water heaters and hot water supply boilers having a capacity of 10 gallons or more are required to undergo the same standby loss test that is prescribed in Exhibit G.2 of ANSI Z21.10.3–2011. However, in this NOPR, DOE is proposing a new and separate standby loss test procedure for flow-activated instantaneous water heaters.

In the proposed standby loss test procedure, the flow-activated instantaneous water heater being tested would not cycle on at any point in the course of the test. Therefore, the amount of fuel consumption is not needed for standby loss calculations. This modification will simplify the test and reduce the amount of data processing required for calculating standby loss metric. As a result, this modification would be beneficial to all manufacturers, including small businesses.

The second difference pertains to the duration of the test. In the current test procedure, the equipment is tested until the first cut-out that occurs after 24 hours or 48 hours, whichever comes first. In the proposed standby loss test procedure for flow-activated instantaneous water heaters, the test ends when the outlet water temperature drops by 35 °F or after 24 hours, whichever comes first. DOE has tentatively concluded that it is very likely that a 35 °F drop in outlet water temperature will occur before 24 hours. Therefore, this proposed modification would likely be beneficial to all manufacturers, including small businesses, as it would reduce the time required to conduct the standby loss test. In addition, DOE notes that the maximum test length of 24 hours in the proposed test method is the same as the current minimum test length in the existing test procedure, so the proposed test would always result in a test length either shorter or equal to that of the current test.

The third difference is with regards to the measurement recording intervals. In the current test procedure, the time interval between two successive readings is 1 minute for the thermal efficiency test and 15 minutes for a standby loss test. In the proposed standby loss test method for flow-activated instantaneous water heaters, DOE has proposed to shorten the time interval to 30 seconds. As with other types of CWH equipment, because manufacturers are already required to measure at one-minute intervals for the thermal efficiency test, DOE believes that manufacturers already use a computer-connected data acquisition system. Changing the time intervals for recording measurements on a data acquisition system is a quick process that requires the operator to simply change the parameters on the computer using the data acquisition system software. Therefore, DOE believes that manufacturers would not incur any additional testing costs due to the proposed changes in the data recording time intervals.

In summary, DOE has tentatively concluded that the proposed standby loss test procedure for flow-activated water heaters would not impose any significant additional burden on manufacturers, including small businesses.

Changes to the Test Set-Up for Instantaneous Water Heaters and Hot Water Supply Boilers

For the thermal efficiency and standby loss tests of instantaneous water heaters and hot water supply boilers, DOE proposes to move the outlet water temperature-sensing location closer to the CWH equipment being tested, with several requirements for the placement of the temperature-sensing probe in the outlet water line. DOE also proposes to require the supply water valve be within a distance of 5 inches and an outlet water valve be within a distance of 10 inches from the water heater jacket. These modifications in the test set-up would require: (1) Moving the tee pipe fitting that is used to hold the outlet water temperature sensing instrument to a location immediately outside the CWH equipment; and (2) moving the supply water valve and outlet water valve that are already installed further away from the water heater to the a location closer to the CWH equipment. In case a new tee is required, DOE estimates that such a fitting would cost approximately $50. DOE reasons that the benefits of better representation of the outlet water temperature and close proximity of the water valves that need to be shut off to retain the hot water in the water heater during the standby loss test outweighs the small potential cost of an additional pipe fitting. In addition to these changes, DOE also proposes to clarify the conditions for using a recirculating loop. The use of a recirculating loop is allowed in the current test procedure, and, thus, this modification would not cause an increase in testing cost. Therefore, DOE has tentatively concluded that the adjustments described in this paragraph would not impose a significant burden on manufacturers, including small businesses.

Modified Standby Loss Test Procedure for Instantaneous Water Heaters and Hot Water Supply Boilers

DOE's current standby loss test procedure for CWH equipment at 10 CFR 431.106, which incorporates by reference Exhibit G.2 of ANSI Z21.10.3–2011, requires the measurement of the mean tank temperature to calculate standby loss. In this NOPR, DOE proposes to replace the measurement of mean tank temperature with the outlet water temperature for conducting the standby loss test for instantaneous water heaters and hot water supply boilers that do not meet DOE's proposed definition of "storage-type instantaneous water heater." This proposed modification to the current test procedure would only change the terms that are used in calculating standby loss. The recording of the outlet water temperature is already required in the thermal efficiency test procedure for all CWH equipment. Therefore, the only change that the manufacturers would be required to make would be to record the outlet water temperature during the standby loss test. Accordingly, DOE has tentatively concluded that these proposed changes would not be unduly burdensome to manufacturers, including small businesses.

Commercial Heat Pump Water Heaters

DOE currently does not prescribe a test procedure for commercial heat pump water heaters. In this NOPR, DOE proposes to adopt a new test procedure for measurement of the COP_h of CHPWHs. If this test procedure is adopted, certification of COP_h for CHPWHs would not be required unless and until DOE establishes energy conservation standards for this class in terms of COP_h. However, DOE acknowledges that in the absence of a Federal COP_h standard, some manufacturers may choose to rate the efficiency of their commercial heat pump water heaters to help distinguish their equipment from competitor offerings.

DOE believes that manufacturers of CHPWHs already have the equipment, instrumentation, and facilities (including psychrometric chambers) for testing their units according to the proposed test method, because these would be needed for product development and measurement of COP_h values absent a DOE test method. However, DOE acknowledges that some manufacturers may need to purchase equipment, instrumentation, or test stands for measurement of COP_h according to the proposed test method. For testing air-source CHPWH units, DOE estimates that the cost to build a test stand and a surrounding psychrometric chamber for the testing of CHPWHs would cost no more than $300,000. While the duration of the proposed test for air-source CHWPHs is 30 minutes, DOE estimates the total time, including the time needed for set-up and stabilizing the outlet water temperatures prior to the test, may reach five hours. At a rate of $40 per hour for a laboratory technician, DOE estimates the cost for this labor would be $200 per model tested.

Given the small market size of air-source CHPWHs, DOE believes that most manufacturers without test facilities capable of testing air-source CHPWHs according to DOE's proposed test procedure would choose to conduct testing at a third-party lab. DOE estimates that the average air-source CHPWH manufacturer sells six models, and that the cost of testing an air-source CHPWH would not exceed $10,000. Therefore, the average testing burden for manufacturers of air-source CHPWHs without testing facilities should not exceed $60,000.

For indoor water-source and ground water-source CHPWHs, water solution conditioning and recirculation equipment similar to a chiller would be required for testing, in addition to equipment needed for testing air-source CHPWHs (*e.g.,* standard piping, instrumentation, a data acquisition system, and test stand). DOE expects most manufacturers already have such equipment in order to test and provide ratings for their current product offerings. However, DOE acknowledges that there may be some manufacturers that do not currently have equipment sufficient for conducting DOE's proposed test procedure. DOE estimates the total cost of a chiller to be about $20,000. The cost of instrumentation, piping, and a data acquisition unit could add up to an additional $5,000. Therefore, DOE does not expect capital investments would exceed $25,000 per manufacturer. DOE estimates that following the test procedure, it would take approximately 5–6 hours to set up the unit and to conduct the test. At a lab technician labor cost of $40 per hour, DOE estimates the total labor cost incurred to test each unit would be between $200 and $240. Alternatively, some manufacturers, including small businesses, may choose to test their units at third-party laboratories instead of investing in in-house testing facilities. DOE estimates that the cost of such testing would not exceed $3,000 per unit. DOE estimates that manufacturers may test about 6 models annually at third-party laboratories. Therefore, the total estimated cost burden for any such manufacturers would not be more than $18,000.

Based on the proposed test procedure, the test set-up for ground or indoor water-source CHPWHs would be similar to that for direct geo-exchange CHPWHs, with the only difference being that the test set-up for direct geo-exchange CHPWHs includes an additional solution heat exchanger. Similar to water-source CHPWHs, DOE expects that most manufacturers of direct geo-exchange CHPWHs already have such equipment in order to test and provide ratings for their current product offerings. DOE understands that the cost of this solution heat exchanger would be the only cost to be added to the total estimated cost for testing ground and indoor water-source CHPWHs in order to arrive at the estimated cost of testing a direct geo-exchange CHPWH. DOE estimates the cost of a liquid-to-liquid heat exchanger to be not more than $30,000. Therefore, the total estimated capital investment cost for testing a direct geo-exchange CHPWH would not exceed $55,000. Similar to water-source CHPWH manufacturers, DOE understands that many manufacturers of direct geo-exchange CHPWHs, including small businesses, may choose to test their units at third-party laboratories instead of investing in in-house testing facilities. DOE estimates the cost of such testing would not exceed $5,000 per unit.

Default Values for Certain Test Parameters

In this NOPR, DOE proposes to add to its test procedure at 10 CFR 431.106 default values for certain test parameters for CWH equipment, to be used if manufacturers do not report these in either the product literature that is shipped with the unit (*e.g.,* installation and operations manual), or their supplemental instructions. DOE proposes the following default values: (1) A maximum allowable water pressure for all CWH equipment; (2) an allowable gas pressure range for gas-fired CWH equipment; and (3) fuel pump pressure and a range for CO_2 reading for oil-fired CWH equipment.

DOE does not expect the proposed default values to present a significant burden to manufacturers because these are basic parameters needed for proper use of CWH equipment and are, therefore, typically specified in manufacturer literature shipped with the unit.

3. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being proposed in this document.

4. Significant Alternatives to the Proposed Rule

DOE considered alternative test methods and modifications to the test procedures for CWH equipment, and tentatively determined that there are no better alternatives than the modifications and procedures proposed in this NOPR. DOE examined relevant industry test standards, and incorporated these standards in the proposed test procedures whenever appropriate to reduce test burden to manufacturers. Specifically, this NOPR updates its test procedures for CWH equipment to incorporate by reference the following updated standards: ASTM D2156–09, ASTM C177–13, ASTM C518–10, and Annex E.1 of ANSI Z21.10.3–2015. Additionally, DOE proposes three new test procedures in this NOPR: A standby loss test procedure for UFHWSTs, a standby loss test procedure for flow-activated instantaneous water heaters, and a test procedure for measurement of COP_h of CHPWHs. For the COP_h test for CHPWHs and the standby loss test for UFHWSTs, DOE proposes to incorporate by reference industry-accepted test methods (ASHRAE 118.1–2012 and sections 4, 5, 6.0, and 6.1 of GAMA Testing Standard IWH–TS–1, respectively). For the standby loss test procedure for flow-activated instantaneous water heaters, DOE proposes a test procedure similar to that recommended by AHRI in supplemental public comments to the February 2014 RFI, with modifications.

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of CWH equipment must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for CWH equipment, including any amendments adopted for those test procedures, on the date that compliance is required. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including CWH equipment. 76 FR 12422 (March 7, 2011); 80 FR 5099 (Jan. 30, 2015). The collection-of-information requirement for certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this proposed rule, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for commercial water heating equipment. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this proposed rule would amend the existing test procedure without affecting the amount, quality, or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion (CX) A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, DOE has made a CX determination for this rulemaking, and neither an environmental assessment nor an environmental impact statement is required. DOE's CX determination for this proposed rule is available at: *http://energy.gov/nepa/categorical-exclusion-cx-determinations-cx/.*

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has tentatively determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the equipment that is the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) Therefore, Executive Order 13132 requires no further action.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and tentatively determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. (This policy is also available at *www.energy.gov/gc/office-general-counsel* under "Guidance & Opinions" (Rulemaking)) DOE examined the proposed rule according to UMRA and its statement of policy and has tentatively determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year. Accordingly, no further assessment or analysis is required under UMRA.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," 53 FR 8859 (March 18, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with the applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has tentatively concluded that the regulatory action in this document, which proposes amendments to the test procedure for measuring the energy efficiency of commercial water heating equipment, is not a significant energy action because it is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects for this proposed rule.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101 *et seq.*), DOE must comply with all laws applicable to the former Federal Energy Administration, including section 32 of the Federal Energy Administration Act of 1974 (Pub. L. 93–275), as amended by the Federal Energy Administration Authorization Act of 1977 (Pub. L. 95–70). (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

This proposed rule incorporates testing methods contained in the following commercial standards: (1) GAMA IWH–TS–1, "Method to Determine Performance of Indirect-Fired Water Heaters," March 2003 edition, sections 4, 5, 6.0, and 6.1; (2) ANSI Z21.10.3–2015/CSA 4.3–2015, "Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous," annex E.1; (3) ANSI/ASHRAE Standard 118.1–2012, "Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water-Heating Equipment"; (4) ASTM D2156–09, "Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels"; (5) ASTM C177–13, "Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus"; and (6) ASTM C518–10, "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus." While the proposed test procedures are not exclusively based on these standards, DOE's test procedures would adopt several provisions from these standards without amendment. The Department has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA, (*i.e.*, that they were developed in a manner that fully provides for public participation, comment, and review). DOE will consult with the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference the following test standards:

(1) GAMA IWH–TS–1, "Method to Determine Performance of Indirect-Fired Water Heaters," March 2003 edition, sections 4, 5, 6.0, and 6.1;

(2) ANSI Z21.10.3–2015/CSA 4.3–2015, "Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous," annex E.1;

(3) ANSI/ASHRAE Standard 118.1–2012, "Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water-Heating Equipment";

(4) ASTM D2156–09, "Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels";

(5) ASTM C177–13, "Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus"; and

(6) ASTM C518–10, "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus."

GAMA IWH–TS–1 (March 2003 edition) is an industry-accepted test procedure for measuring the performance of indirect water heaters. In this NOPR, DOE proposes to incorporate by reference sections of this test procedure that address test set-up, instrumentation, and test conditions. GAMA IWH–TS–1, March 2003 edition, is available on AHRI's[28] Web site at *http://www.ahrinet.org/App_Content/ahri/files/standards%20pdfs/Indirect-Fired%20Water%20Heater%20Testing%20Standard03.pdf.*

ANSI Z21.10.3–2015/CSA 4.3–2015 is an industry-accepted test procedure for measuring the performance of commercial water heaters. In this NOPR, DOE proposes to incorporate by reference sections of this test procedure that address test set-up, instrumentation, test conditions, and test conduct. ANSI Z21.10.3–2015/CSA 4.3–2015 is available on ANSI's Web site at *http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI+Z21.10.3-2015%2fCSA4.3-2015.*

ANSI/ASHRAE Standard 118.1–2012 is an industry-accepted test procedure for measuring the performance of commercial water heaters. ANSI/ASHRAE 118.1–2012 is available on ANSI's Web site at *http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2FASHRAE+Standard+118.1-2012.*

ASTM D2156–09 is an industry-accepted test procedure for determining the smoke spot number of flue gases. ASTM D2156–09 is available on ASTM's Web site at *http://www.astm.org/Standards/D2156.htm.*

ASTM C177–13 is an industry-accepted test procedure for determining the R-value of a sample using a guarded-hot-plate apparatus. ASTM C177–13 is available on ASTM's Web site at *http://www.astm.org/Standards/C177.htm.*

ASTM C518–10 is an industry-accepted test procedure for determining the R-value of a sample using a heat flow meter apparatus. ASTM C518–10 is available on ASTM's Web site at *http://www.astm.org/Standards/C518.htm.*

V. Public Participation

A. Attendance at the Public Meeting

The time, date, and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. If you plan to attend the public meeting, please notify Ms. Brenda Edwards at (202) 586–2945 or *Brenda.Edwards@ee.doe.gov.* All participants will undergo security processing upon building entry, and foreign nationals visiting DOE Headquarters are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building must undergo additional screening and will be required to obtain a property pass. Visitors should avoid bringing laptops, or allow an extra 45 minutes to check in. Please report to the visitors desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding identification (ID) requirements for individuals wishing to enter Federal buildings from specific States and U.S. territories. As a result, driver's licenses from the following States or territory will not be accepted for building entry, and instead, one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, American Samoa, Arizona, Louisiana, Maine, Massachusetts, Minnesota, New York, Oklahoma, and Washington.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the States of Minnesota, New York or Washington (Enhanced licenses issued by these States are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government-issued Photo-ID card.

In addition, attendees may participate in the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's Web site at: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=36.* Participants are responsible for ensuring their systems are compatible with the webinar software.

The purpose of the meeting is to receive oral and written comments, data, and other information that would provide understanding about potential issues associated with this rulemaking. DOE must receive requests to speak at the meeting before 12:00 a.m. EST, June 3, 2016. DOE must receive a signed original and an electronic copy of any statement to be given at the public meeting before 12:00 a.m. EST, June 3, 2016.

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[28] ARI and GAMA merged to become AHRI on January 1, 2008.

B. Procedure for Submitting Requests To Speak and Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this document, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the public meeting. Such persons may hand-deliver requests to speak to the address shown in the **ADDRESSES** section at the beginning of this document between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays. Requests may also be sent by mail or email to Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121, or *Brenda.Edwards@ee.doe.gov.* Persons who wish to speak should include with their request a computer diskette or CD–ROM in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

DOE requests persons scheduled to make an oral presentation to submit an advance copy of their statements at least one week before the public meeting. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral presentation should ask for such alternative arrangements.

C. Conduct of the Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the public meeting and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document and will be accessible on the DOE Web site. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this notice of proposed rulemaking.

Submitting comments via www.regulations.gov. The *www.regulations.gov* Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section which follows.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or mail. Comments and documents submitted via email, hand delivery/courier, or mail also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery/courier, please provide all items on a

CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption, and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked "confidential" including all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

Issue 1: DOE seeks comment on its proposed incorporation by reference of ASTM D2156–09, and on its proposed additional specifications for how to set up the smoke spot test, and when to conduct the smoke spot test and measure the CO_2 reading.

Issue 2: DOE seeks comment on its proposed incorporation by reference of ASTM C177–13 and C518–10 for the definition of "R-value."

Issue 3: DOE requests comments and data on its proposed changes to improve the repeatability of the thermal efficiency and standby loss test procedures for certain commercial water heating equipment. Specifically, DOE requests comment on its proposed requirements for ambient relative humidity. DOE does not propose this requirement for testing of electric water heaters, and seeks feedback on whether including such a requirement would improve the repeatability of the standby loss test for electric water heaters. DOE is also seeking comments regarding any additional changes that would improve the repeatability of the thermal efficiency and standby loss tests.

Issue 4: DOE requests comment on the changes to improve test repeatability for its test procedures for certain CWH equipment that were identified but not proposed in this NOPR. If comments suggest that DOE should implement these changes, then DOE will evaluate whether it can adopt those changes in the final rule or must engage in further rulemaking. Particularly, DOE requests data showing what duration for the steady-state verification period would ensure steady-state operation is reached for gas-fired and oil-fired CWH equipment prior to the thermal efficiency test. DOE also seeks data that suggest suitable tolerances for water temperature and flow rate for this steady-state verification period. Additionally, DOE seeks comment on whether different requirements for establishing steady-state operation are warranted for each equipment class of CWH equipment.

Issue 5: DOE requests comment on the proposed test procedure to determine the standby loss for UFHWSTs, and on whether any other methods, including those detailed in this NOPR, would lead to a better test. Specifically, DOE solicits feedback on whether the proposed test would be long enough to determine an accurate standby loss rating, whether the use of a linear approximation of the temperature decay is sufficient to estimate the standby loss, whether running the test by simply letting the temperature decay (rather than providing external heat to bring the temperature of the water back to operational temperature) is appropriate, and whether the adoption of test conditions (*i.e.,* ambient room temperature, maximum air draft, water temperature) similar to that of other classes of CWH equipment is appropriate. DOE also seeks comment on whether any of its identified alternatives could be modified to improve their repeatability and to decrease test burden, thereby supporting further consideration.

Issue 6: DOE seeks comment on its proposed change to its requirements for setting the tank thermostat in the thermal efficiency and standby loss test procedures for gas-fired and oil-fired storage and storage-type instantaneous water heaters from measurement of mean tank temperature to measurement of outlet water temperature.

Issue 7: DOE seeks comment on its tentative decision to maintain a mean tank temperature requirement for the standby loss test for electric storage water heaters. DOE also requests comment on its clarifying language for setting tank thermostats for electric storage water heaters with multiple thermostats.

Issue 8: DOE requests comment on its proposed clarifying statements regarding steady-state operation and manipulation of CWH equipment settings during efficiency tests.

Issue 9: DOE requests comment on its proposal to remove exemptions from the definitions for consumer water heaters codified at 10 CFR 430.2 that exclude units that heat water to temperatures greater than 180 °F and units with a storage capacity greater than 120 gallons. DOE also requests comment on its proposal to remove the definitions at 10 CFR 430.2 for "electric heat pump water heater" and "gas-fired heat pump water heater."

Issue 10: DOE requests comment on its proposed changes to its definitions for CWH equipment: (1) Replacing the terms "rated input" and "input rating" with "fuel input rate" for gas-fired and oil-fired CWH equipment to match DOE's proposed definition for "fuel input rate;" (2) modifying DOE's definitions for "instantaneous water heater" and "storage water heater" by adding the input criteria that separate consumer water heaters and commercial water heaters and removing several phrases that do not serve to clarify coverage of units under the definitions;

and (3) removing the definition of "packaged boiler."

Issue 11: DOE requests comment on its proposal to modify the definition of "residential-duty commercial water heater" by removing from its scope the following classes: Electric storage water heaters, heat pump water heaters with storage, gas-fired instantaneous water heaters, and oil-fired instantaneous water heaters.

Issue 12: DOE seeks comment on its proposed definition of "storage-type instantaneous water heater."

Issue 13: DOE requests comment on its proposed definition for "flow-activated instantaneous water heater." Specifically, DOE requests feedback on whether the definition includes all units and designs for which a separate standby loss test procedure is warranted, and whether any units would be included that do not need a test method separate from the current standby loss test procedure for CWH equipment.

Issue 14: DOE requests comment on its proposal to include a test procedure similar to that specified in section 5.27 of ANSI Z21.10.3–2015 for measuring the storage volume of all instantaneous water heaters and hot water supply boilers, including flow-activated instantaneous water heaters. DOE also seeks information on alternative methods for measuring storage volume and the impact of residual water on measuring storage volume of instantaneous water heaters and hot water supply boilers. Further, DOE seeks comment on ways to remove residual water from the water heater that could allow for more accurate and consistent measurement of the storage volume of CWH equipment.

Issue 15: DOE requests comment from interested parties on all aspects of the proposed test procedure for flow-activated instantaneous water heaters. Specifically, DOE requests comment on its tentative decision to: (1) Base the test procedure on the second part of the 2016 AHRI-recommended test method that applies to flow-activated water heaters that will not initiate burner operation over the course of the test; (2) stop the test following a 35 °F ± 2 °F drop in the outlet water temperature or completion of 24 hours, whichever occurs earlier; and (3) use the outlet water temperature as an approximation of the stored water temperature.

Issue 16: DOE seeks comment on its proposed change to the location of temperature measurement for the outlet water temperature with the associated conditions for placement of temperature-sensing instruments in water pipes, as well as the placement of the supply and outlet water valves. Specifically, DOE requests comment on whether such a change would provide more accurate test results, and whether the change would be burdensome to manufacturers. Additionally, DOE requests information on any alternative arrangements to measure the outlet water temperature accurately and in close proximity to the hot water outlet of the tested CWH equipment.

Issue 17: DOE requests comment on the proposed test procedure for instantaneous water heaters and hot water supply boilers (except those meeting the proposed definition of "storage-type instantaneous water heater" and "flow-activated instantaneous water heater"). DOE also requests feedback on its tentative decision to use the outlet water temperature instead of the mean tank temperature or stored water temperature to conduct the standby loss test. Further, DOE requests suggestions on methods or approaches that can be used to measure the stored water temperature accurately.

Issue 18: DOE requests comment on its proposed definition for "commercial heat pump water heater."

Issue 19: DOE requests comment on the proposed categories of CHPWHs and related definitions. In particular, DOE requests comments on CHPWH heat sources that are currently available for commercial applications.

Issue 20: DOE requests comment on all aspects of the proposed test procedure for commercial heat pump water heaters, and in particular, the proposal to test all units without a storage tank. DOE also invites comment on its recommended rating conditions, particularly the supply water temperatures for air-source commercial heat pump water heaters.

Issue 21: DOE seeks comment regarding its proposed definition and methodology for measuring and verifying fuel input rate for gas-fired and oil-fired CWH equipment.

Issue 22: DOE requests comment on its proposed default values for maximum water supply pressure for all equipment, allowable gas supply pressure range for equipment powered with natural gas and propane, and the CO_2 reading and fuel pump pressure for oil-fired equipment.

Issue 23: DOE requests comment on its proposed additional certification requirements for instantaneous water heaters and hot water supply boilers, and seeks feedback on any other information that should be included for any classes of CWH equipment.

Issue 24: DOE requests comment on its cost estimates for manufacturers to test their unfired hot water storage tanks according to DOE's proposed test method.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking.

List of Subjects

10 CFR Part 429

Confidential business information, Energy conservation, Household appliances, Imports, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

10 CFR Part 431

Administrative practice and procedure, Confidential business information, Incorporation by reference, Test procedures, Reporting and recordkeeping requirements.

Issued in Washington, DC, on April 15, 2016.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE proposes to amend parts 429, 430, and 431 of chapter II, subchapter D of title 10, Code of Federal Regulations, as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 429.44 is amended by:
■ a. Revising paragraphs (b) and (c);
■ b. Redesignating paragraph (d) as (e) and revising newly redesignated paragraph (e); and
■ c. Adding and reserving a new paragraph (d).

The additions and revisions read as follows:

§ 429.44 Commercial water heating equipment.

* * * * *

(b) *Determination of represented values for all types of commercial water heaters except residential-duty* *commercial water heaters.* Manufacturers must determine the represented values, which includes the certified ratings, for each basic model of commercial water heating equipment except residential-duty commercial water heaters, either by testing, in conjunction with the applicable sampling provisions, or by applying an AEDM as set forth in § 429.70.

(1) *Units to be tested.* If the represented value for a given basic model is determined through testing:

(i) The general requirements of § 429.11 apply; and

(ii) A sample of sufficient size must be randomly selected and tested to ensure that:

(A) Any represented value of energy consumption or other measure of energy use of a basic model for which consumers would favor lower values must be greater than or equal to the higher of:

(*1*) The mean of the sample, where:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

And, $\bar{x}$ is the sample mean; n is the number of samples; and x_i is the ith sample; or,

(*2*) The upper 95 percent confidence limit (UCL) of the true mean divided by 1.05, where:

$$UCL = \bar{x} + t_{.95}\left(\frac{s}{\sqrt{n}}\right)$$

And $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with n − 1 degrees of freedom (from appendix A to subpart B of this part). And,

(B) Any represented value of energy efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values must be less than or equal to the lower of:

(*1*) The mean of the sample, where:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

And, $\bar{x}$ is the sample mean; n is the number of samples; and x_i is the ith sample; or,

(*2*) The lower 95 percent confidence limit (LCL) of the true mean divided by 0.95, where:

$$LCL = \bar{x} - t_{.95}\left(\frac{s}{\sqrt{n}}\right)$$

And $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with n − 1 degrees of freedom (from appendix A to subpart B of this part).

(2) *Alternative efficiency determination methods.* In lieu of testing, a represented value of efficiency or consumption for a basic model must be determined through the application of an AEDM pursuant to the requirements of § 429.70 and the provisions of this section, where:

(i) Any represented value of energy consumption or other measure of energy use of a basic model for which consumers would favor lower values must be greater than or equal to the output of the AEDM and less than or equal to the Federal standard for that basic model; and

(ii) Any represented value of energy efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values must be less than or equal to the output of the AEDM and greater than or equal to the Federal standard for that basic model.

(3) The representative value of fuel input rate of a basic model reported in accordance with paragraph (c)(2) of this section must be either the mean of the fuel input rate(s) measured for each tested unit of the basic model and determined in accordance with the test procedure in § 431.106 of this chapter, or the value determined with an AEDM, and rounded to the nearest 1,000 Btu/h.

(c) *Certification reports.* For commercial water heating equipment other than residential-duty commercial water heaters:

(1) The requirements of § 429.12 apply; and

(2) Pursuant to § 429.12(b)(13), a certification report must include the following public equipment-specific information:

(i) Commercial electric storage water heaters: The standby loss in percent per hour (%/h) and the measured storage volume in gallons (gal).

(ii) Commercial gas-fired and oil-fired storage water heaters: The thermal efficiency in percent (%), the standby loss in British thermal units per hour (Btu/h), the rated storage volume in gallons (gal), and the fuel input rate in British thermal units per hour (Btu/h) rounded to the nearest 1,000 Btu/h.

(iii) Commercial water heaters and hot water supply boilers with storage capacity greater than 140 gallons: The thermal efficiency in percent (%), whether the storage volume is greater than 140 gallons (Yes/No); whether the tank surface area is insulated with at least R–12.5 (Yes/No); whether a standing pilot light is used (Yes/No); for gas or oil-fired water heaters, whether the basic model has a fire damper or fan-assisted combustion (Yes/No); and, if applicable, pursuant to 10 CFR 431.110, the standby loss in British thermal units per hour (Btu/h) and measured storage volume in gallons (gal).

(iv) Commercial gas-fired and oil-fired instantaneous water heaters with storage capacity greater than or equal to 10 gallons and gas-fired and oil-fired hot water supply boilers with storage capacity greater than or equal to 10 gallons: The thermal efficiency in percent (%), the standby loss in British thermal units per hour (Btu/h); the rated storage volume in gallons (gal); the fuel input rate in British thermal units per hour (Btu/h) rounded to the nearest 1,000 Btu/h; whether a submerged heat exchanger is used (Yes/No); and whether flow through the water heater is required to initiate burner ignition (Yes/No).

(v) Commercial gas-fired and oil-fired instantaneous water heaters with storage capacity less than 10 gallons and gas-fired and oil-fired hot water supply boilers with storage capacity less than 10 gallons: The thermal efficiency in percent (%), the rated storage volume in gallons (gal), and the fuel input rate in British thermal units per hour (Btu/h) rounded to the nearest 1,000 Btu/h.

(vi) Commercial unfired hot water storage tanks: The thermal insulation (*i.e.*, R-value) and stored volume in gallons (gal).

(3) Pursuant to § 429.12(b)(13), a certification report must include the following additional, equipment-specific information:

(i) Whether the basic model is engineered-to-order; and

(ii) For any basic model rated with an AEDM, whether the manufacturer elects the witness test option for verification testing. (See § 429.70(c)(5)(iii) for options.) However, the manufacturer may not select more than 10 percent of AEDM-rated basic models to be eligible for witness testing.

(4) Pursuant to § 429.12(b)(13), a certification report may include supplemental testing instructions in PDF format. If necessary to run a valid test, the equipment-specific, supplemental information must include any additional testing and testing set-up instructions (*e.g.*, whether a bypass loop was used for testing) for the basic model and all other information (*e.g.*, operational codes or overrides for the control settings) necessary to operate the

basic model under the required conditions specified by the relevant test procedure. A manufacturer may also include with a certification report other supplementary items in PDF format for DOE's consideration in performing testing under subpart C of this part. For example, for gas-fired commercial water heating equipment (other than residential-duty commercial water heaters): The maximum water pressure in pounds per square inch (psi), and the minimum and maximum gas supply pressure in inches of water column (in. w.c.)—including the gas pressure specifications for both natural gas and propane, if models powered by both natural gas and propane are certified under the same basic model; or for oil-fired commercial water heating equipment (other than residential-duty commercial water heaters): The maximum water pressure in pounds per square inch (psi), the allowable range for CO_2 reading in percent (%), and the fuel pump pressure in pounds per square inch gauge (psig); or for electric commercial water heating equipment (other than residential-duty commercial water heaters): The maximum water pressure in pounds per square inch (psi).

(d) [Reserved]

(e) Alternative methods for determining efficiency or energy use for commercial water heating equipment can be found in § 429.70.

■ 3. Section 429.134 is amended by adding paragraph (m) to read as follows:

§ 429.134. Product-specific enforcement provisions.

* * * * *

(m) *Commercial water heating equipment other than residential-duty commercial water heaters*—(1) *Verification of fuel input rate.* The fuel input rate of each tested unit of the basic model will be measured pursuant to the test requirements of § 431.106 of this chapter. The measured fuel input rate (either the measured fuel input rate for a single unit sample or the average of the measured fuel input rates for a multiple unit sample) will be compared to the value of fuel input rate certified by the manufacturer. The certified fuel input rate will be considered valid only if the measured fuel input rate is within two percent of the certified fuel input rate.

(i) If the certified fuel input rate is found to be valid, then the certified fuel input rate will serve as the basis for determination of the appropriate equipment class and calculation of the standby loss standard (as applicable).

(ii) If the measured fuel input rate is not within two percent of the certified fuel input rate, attempt to achieve the certified fuel input rate (within two percent), DOE will first attempt to increase or decrease the gas pressure within the range specified in manufacturer's instructions in the installation and operation manual shipped with the commercial water heating equipment being tested or in supplemental instructions provided by the manufacturer. If the gas pressure range is not specified by the manufacturer in either of these sources, DOE will use the default range for gas pressure included in appendices A, C, and E to subpart G of part 431 of this chapter. If the measured fuel input rate is still not within two percent of the certified fuel input rate, DOE will attempt to modify the gas inlet orifice. If the measured fuel input rate still is not within two percent of the certified fuel input rate, the measured fuel input rate will serve as the basis for determination of the appropriate equipment class and calculation of the standby loss standard (as applicable).

(2) [Reserved]

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 4. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 5. Section 430.2 is amended by:

■ a. Removing the definitions of "Electric heat pump water heater" and "Gas-fired heat pump water heater"; and

■ b. Revising the definitions of "Electric instantaneous water heater," "Electric storage water heater," "Gas-fired instantaneous water heater," "Gas-fired storage water heater," "Oil-fired instantaneous water heater," and "Oil-fired storage water heater."

The revisions read as follows:

§ 430.2 Definitions.

* * * * *

Electric instantaneous water heater means a water heater that uses electricity as the energy source, has a nameplate input rating of 12 kW or less, and contains no more than one gallon of water per 4,000 Btu per hour of input.

* * * * *

Electric storage water heater means a water heater that uses electricity as the energy source, has a nameplate input rating of 12 kW or less, and contains more than one gallon of water per 4,000 Btu per hour of input.

* * * * *

Gas-fired instantaneous water heater means a water heater that uses gas as the main energy source, has a nameplate input rating less than 200,000 Btu/h, and contains no more than one gallon of water per 4,000 Btu per hour of input.

Gas-fired storage water heater means a water heater that uses gas as the main energy source, has a nameplate input rating of 75,000 Btu/h or less, and contains more than one gallon of water per 4,000 Btu per hour of input.

* * * * *

Oil-fired instantaneous water heater means a water heater that uses oil as the main energy source, has a nameplate input rating of 210,000 Btu/h or less, and contains no more than one gallon of water per 4,000 Btu per hour of input.

Oil-fired storage water heater means a water heater that uses oil as the main energy source, has a nameplate input rating of 105,000 Btu/h or less, and contains more than one gallon of water per 4,000 Btu per hour of input.

* * * * *

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 6. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 7. Section 431.102 is amended by:

■ a. Revising the section heading;

■ b. Revising the definitions of "Hot water supply boiler," "Instantaneous water heater," "R-value," "Residential-duty commercial water heater," "Standby loss," and "Storage water heater";

■ c. Adding, in alphabetical order, definitions for the terms "Air-source commercial heat pump water heater," "Coefficient of performance," "Commercial heat pump water heater," "Direct geo-exchange commercial heat pump water heater," "Flow-activated instantaneous water heater," "Fuel input rate," "Ground water-source commercial heat pump water heater," "Indoor water-source commercial heat pump water heater," and "Storage-type instantaneous water heater"; and

■ d. Removing the definitions of "ASTM–D–2156–80" and "Packaged boiler."

The revisions and additions read as follows:

§ 431.102 Definitions concerning commercial water heaters, hot water supply boilers, unfired hot water storage tanks, and commercial heat pump water heaters.

Air-source commercial heat pump water heater means a commercial heat pump water heater that utilizes surrounding air as the heat source.

* * * * *

Coefficient of performance (*COP_h*) means the dimensionless ratio of the rate of useful heat transfer gained by the water (expressed in Btu/h), to the rate of electric power consumed during operation (expressed in Btu/h).

Commercial heat pump water heater (CHPWH) means a water heater that uses a refrigeration cycle, such as vapor compression, to transfer heat from a low-temperature source to a higher-temperature sink for the purpose of heating potable water, and has a rated electric power input greater than 12 kW. Such equipment includes, but is not limited to, air-source heat pump water heaters, water-source heat pump water heaters, and direct geo-exchange heat pump water heaters.

Direct geo-exchange commercial heat pump water heater means a commercial heat pump water heater that utilizes the earth as a heat source and allows for direct exchange of heat between the earth and the refrigerant in the evaporator coils.

Flow-activated instantaneous water heater means an instantaneous water heater or hot water supply boiler that does not activate the burner or heating element if no heated water is drawn from the unit.

Fuel input rate means the maximum rate at which gas-fired or oil-fired CWH equipment uses energy as determined using test procedures prescribed under § 431.106.

Ground water-source commercial heat pump water heater means a commercial heat pump water heater that utilizes ground water as the heat source.

Hot water supply boiler means a packaged boiler (defined in § 431.82) that is industrial equipment and that:

(1) Has a fuel input rate (for gas-fired or oil-fired equipment) or input rating (for electric equipment) from 300,000 Btu/h to 12,500,000 Btu/h and of at least 4,000 Btu/h per gallon of stored water;

(2) Is suitable for heating potable water; and

(3) Meets either or both of the following conditions:

(i) It has the temperature and pressure controls necessary for heating potable water for purposes other than space heating; or

(ii) The manufacturer's product literature, product markings, product marketing, or product installation and operation instructions indicate that the boiler's intended uses include heating potable water for purposes other than space heating.

Indoor water-source commercial heat pump water heater means a commercial heat pump water heater that utilizes indoor water as the heat source.

Instantaneous water heater means a water heater that uses gas, oil, or electricity, including:

(1) Gas-fired instantaneous water heaters with a fuel input rate both greater than 200,000 Btu/h and not less than 4,000 Btu/h per gallon of stored water;

(2) Oil-fired instantaneous water heaters with a fuel input rate both greater than 210,000 Btu/h and not less than 4,000 Btu/h per gallon of stored water; and

(3) Electric instantaneous water heaters with an input capacity both greater than 12 kW and not less than 4,000 Btu/h per gallon of stored water.

R-value means the thermal resistance of insulating material as determined using ASTM Standard Test Method C177–13 or C518–10 (incorporated by reference; see § 431.105) and expressed in (°F·ft^2·h/Btu).

Residential-duty commercial water heater means any gas-fired storage, oil-fired storage, or electric instantaneous commercial water heater that meets the following conditions:

(1) For models requiring electricity, uses single-phase external power supply;

(2) Is not designed to provide outlet hot water at temperatures greater than 180 °F; and

(3) Does not meet any of the following criteria:

Water heater type	Indicator of non-residential application
Gas-fired Storage	Fuel input rate >105 kBtu/h; Rated storage volume >120 gallons.
Oil-fired Storage	Fuel input rate >140 kBtu/h; Rated storage volume >120 gallons.
Electric Instantaneous	Rated input >58.6 kW; Rated storage volume >2 gallons.

Standby loss means:

(1) For electric commercial water heating equipment (not including commercial heat pump water heaters), the average hourly energy required to maintain the stored water temperature expressed as a percent per hour (%/h) of the heat content of the stored water above room temperature and determined in accordance with appendix B, D, or E to subpart G of part 431 (as applicable), denoted by the term "S."

(2) For gas-fired and oil-fired commercial water heating equipment, the average hourly energy required to maintain the stored water temperature expressed in British thermal units per hour (Btu/h) based on a 70 °F temperature differential between stored water and ambient room temperature and determined in accordance with appendix A, C, or E to subpart G of part 431 (as applicable), denoted by the term "SL"; or

(3) For unfired hot water storage tanks, the average hourly energy lost from the storage tank when in standby mode expressed in British thermal units per hour (Btu/h) and determined in accordance with appendix G to subpart G of part 431, denoted by the term "SL."

Storage water heater means a water heater that uses gas, oil, or electricity to heat and store water within the appliance at a thermostatically-controlled temperature for delivery on demand, including:

(1) Gas-fired storage water heaters with a fuel input rate both greater than 75,000 Btu/h and less than 4,000 Btu/h per gallon of stored water;

(2) Oil-fired storage water heaters with a fuel input rate both greater than 105,000 Btu/h and less than 4,000 Btu/h per gallon of stored water; and

(3) Electric storage water heaters with an input capacity both greater than 12 kW and less than 4,000 Btu/h per gallon of stored water.

Storage-type instantaneous water heater means an instantaneous water heater comprising a storage tank with a submerged heat exchanger(s) or heating element(s).

* * * * *

§ 431.104 [Removed]

■ 8. Section 431.104 is removed.

■ 9. Section 431.105 is amended by:

■ a. Redesignating paragraph (b) as (c) and revising newly redesignated paragraph (c); and

■ b. Adding paragraphs (b), (d), and (e).

The revisions and additions read as follows:

§ 431.105 Materials incorporated by reference.

* * * * *

(b) *AHRI.* Air-Conditioning, Heating, and Refrigeration Institute, 2111 Wilson Blvd., Suite 500, Arlington, VA 22201, (703) 524–8800, or go to *www.ahrinet.org.*

(1) GAMA Testing Standard IWH–TS–1, "Method to Determine Performance of Indirect-fired Water Heaters," March 2003 edition, sections 4, 5, 6.0, and 6.1, IBR approved for appendix G to this subpart.

(2) [Reserved]

(c) *ANSI.* American National Standards Institute, 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or go to: *http://www.ansi.org.*

(1) ANSI Z21.10.3–2015/CSA 4.3–2015 ("ANSI Z21.10.3–2015"), "Gas-fired Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous," Annex E.1, approved by ANSI on October 5, 2015, IBR approved for appendices A, B, C, D, and E to this subpart.

(2) [Reserved]

(d) *ASHRAE.* American Society of Heating, Refrigerating and Air-conditioning Engineers, 1791 Tullie Circle NE., Atlanta, GA 30329, (800) 527–4723, or go to *https://www.ashrae.org.*

(1) ANSI/ASHRAE Standard 118.1–2012, "Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water-Heating Equipment," approved by ASHRAE on October 26, 2012 and by ANSI on October 27, 2012, IBR approved for appendix F to this subpart.

(2) [Reserved]

(e) *ASTM.* ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, (610) 832–9585, or go to *http://www.astm.org.*

(1) ASTM C177–13, "Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus," approved by ASTM on September 15, 2013, IBR approved for § 431.102.

(2) ASTM C518–10, "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus," approved by ASTM on May 1, 2010, IBR approved for § 431.102.

(3) ASTM D2156–09, "Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels," approved by ASTM on December 1, 2009 and reapproved by ASTM on October 1, 2013, IBR approved for appendices A, C, and E to this subpart.

■ 10. Section 431.106 is revised to read as follows:

§ 431.106 Uniform test method for the measurement of energy efficiency of commercial water heating equipment.

(a) *Scope.* This section contains test procedures for measuring, pursuant to EPCA, the energy efficiency of commercial water heating equipment.

(b) *Testing and calculations.* Determine the energy efficiency of commercial water heating equipment by conducting the applicable test procedure(s):

(1) *Residential-duty commercial water heaters.* Test in accordance with appendix E to subpart B of part 430 of this chapter.

(2) *Commercial water heating equipment other than residential-duty commercial water heaters.* Test covered commercial water heating equipment by following the appropriate test procedures in appendices to subpart G of this part.

(i) *Gas-fired and oil-fired storage water heaters and storage-type instantaneous water heaters.* Test according to appendix A to subpart G of this part.

(ii) *Electric storage water heaters and storage-type instantaneous water heaters.* Test according to appendix B to subpart G of this part.

(iii) *Gas-fired and oil-fired instantaneous water heaters and hot water supply boilers (other than flow-activated instantaneous water heaters and storage-type instantaneous water heaters).* Test according to appendix C to subpart G of this part.

(iv) *Electric instantaneous water heaters (other than flow-activated instantaneous water heaters and storage-type instantaneous water heaters).* Test according to appendix D to subpart G of this part.

(v) *Flow-activated instantaneous water heaters.* Test according to appendix E to subpart G of this part.

(vi) *Commercial heat pump water heaters.* Test according to appendix F to subpart G of this part.

(vii) *Unfired hot water storage tanks.* Test according to appendix G to subpart G of this part.

§ 431.107 [Removed]

■ 11. Section 431.107 is removed.

■ 12. Add appendix A to subpart G of part 431 to read as follows:

Appendix A to Subpart G of Part 431—Uniform Test Method for the Measurement of Thermal Efficiency and Standby Loss of Gas-Fired and Oil-Fired Storage Water Heaters and Storage-Type Instantaneous Water Heaters

Note: Prior to (*date 360 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to the energy use or efficiency of the subject commercial water heating equipment in accordance with the results of testing pursuant to this appendix or the procedures in 10 CFR 431.106 that were in place on January 1, 2016. On and after (date 360 days after date of publication of the test procedure final rule in the **Federal Register**), manufacturers must make any representations with respect to energy use or efficiency of gas-fired and oil-fired storage water heaters and storage-type instantaneous water heaters in accordance with the results of testing pursuant to this appendix to demonstrate compliance with the energy conservation standards at 10 CFR 431.110.

1. General

Determine the thermal efficiency and standby loss (as applicable) in accordance with the following sections of this appendix. Certain sections reference sections of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Where the instructions contained in the sections below conflict with instructions in Annex E.1 of ANSI Z21.10.3–2015, the instructions contained herein control.

2. Test Set-Up

2.1. *Placement of Water Heater.* A water heater for installation on combustible floors is to be placed on a ¾-inch plywood platform supported by three 2 x 4-inch runners. If the water heater is for installation on noncombustible floors, suitable noncombustible material is to be placed on the platform. When the use of the platform for a large water heater is not practical, the water heater may be placed on any suitable flooring. A wall-mounted water heater is to be mounted to a simulated wall section.

2.2. *Heat Trap and Thermocouple Installation.* Inlet and outlet piping must be turned vertically downward from the connections on a tank-type water heater so as to form heat traps. Thermocouples for measuring supply and outlet water temperatures must be installed upstream from the inlet heat trap piping and downstream from the outlet heat trap piping, respectively, in accordance with Figure 1, 2, or 3 (as applicable) of this section. The total vertical piping length between the thermocouple sensing location and the connection port must be equal to 24 inches. For water heaters with vertical connections, the 24 inches of total vertical piping length is divided into 6 inches of vertical piping upstream from the turn for the heat trap and 18 inches downstream from the turn for the heat trap. For water heaters that have vertical connections (top and bottom), the total horizontal piping between the connection port and the thermocouple sensing location must be equal to the distance between the water heater connection port and the edge of the water heater plus 2 inches. For water heaters that have horizontal connections, the total horizontal piping between the water heater connection port and the temperature sensing location must be equal to 6 inches. The water heater must meet the requirements shown in Figure 1, 2, or 3 (as applicable) at all times during the conduct of the thermal efficiency and standby loss tests. Any factory-supplied heat traps must be installed per the installation instructions while ensuring the requirements in Figure 1, 2, or 3 are met. All dimensions specified in Figure 1, 2, and 3 and in this section are measured from the outer surface of the pipes and water heater outer casing (as applicable).

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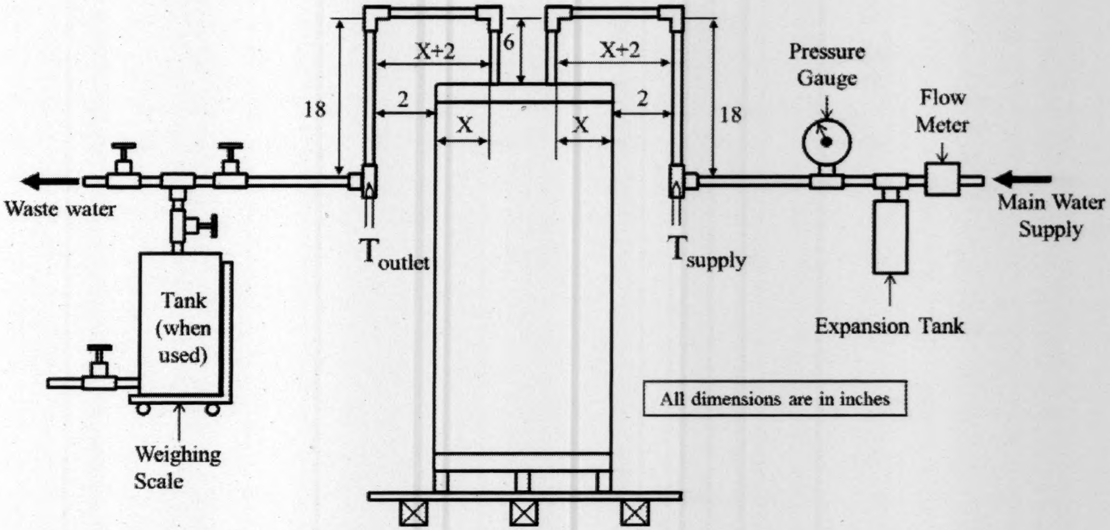
X+2
6
X+2
18
2
X
X
2
18
Pressure Gauge
Flow Meter
Waste water
Main Water Supply
T_{outlet}
T_{supply}
Tank (when used)
Expansion Tank
All dimensions are in inches
Weighing Scale

Figure 1. Set-up for thermal efficiency and standby loss test for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks with vertical (top) connections

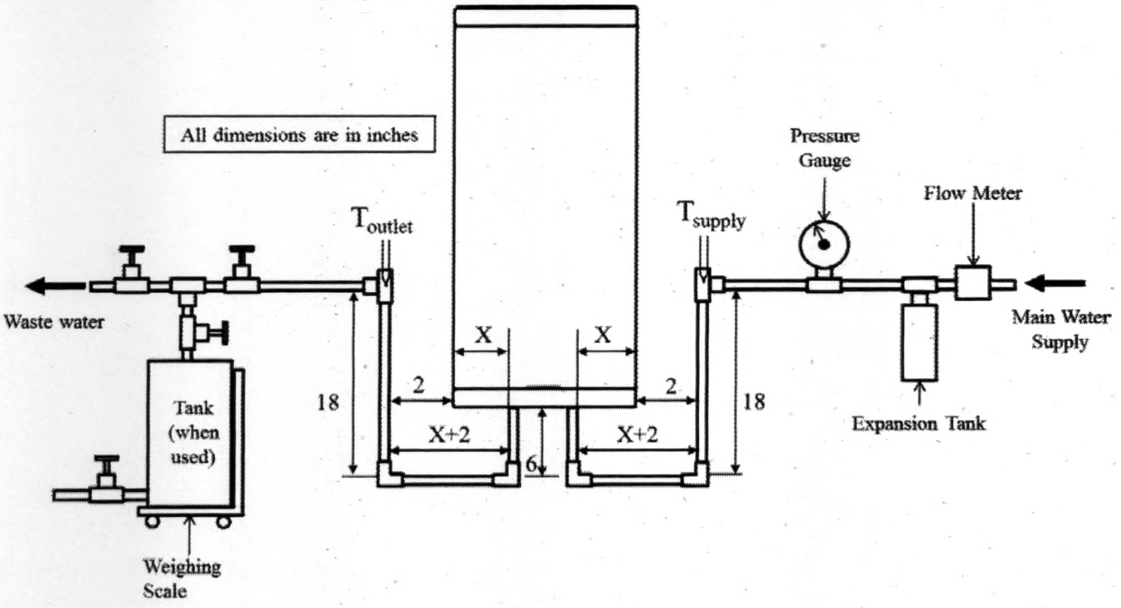
All dimensions are in inches
T outlet
T supply
Pressure Gauge
Flow Meter
Waste water
Main Water Supply
Tank (when used)
Weighing Scale
Expansion Tank
X
X
2
2
18
18
X+2
X+2
6

Figure 2. Set-up for thermal efficiency and standby loss test for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks with vertical (bottom) connections

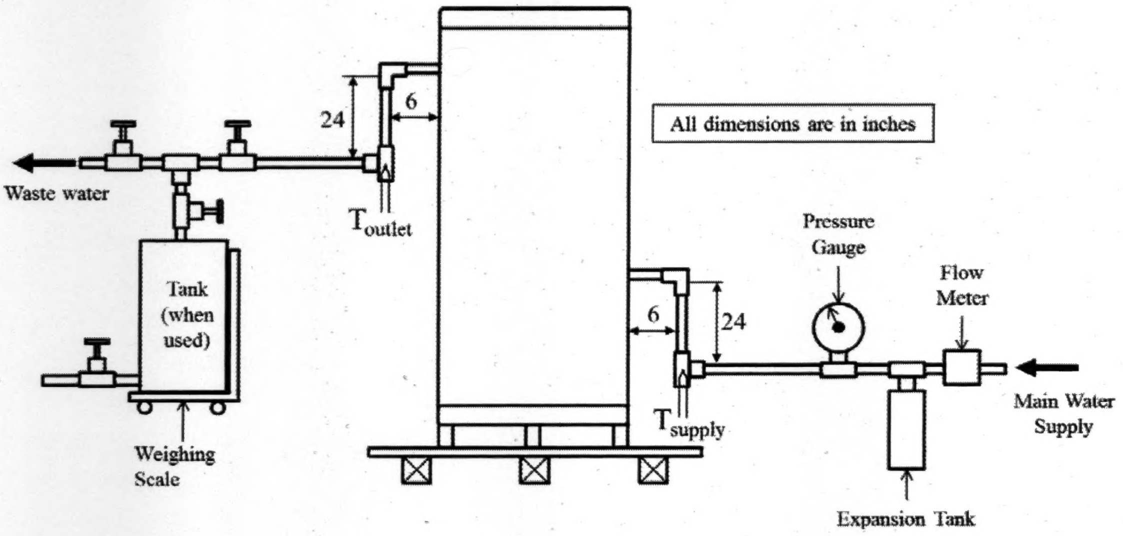
All dimensions are in inches
24
6
Waste water
T outlet
Tank (when used)
Weighing Scale
Pressure Gauge
Flow Meter
6
24
Main Water Supply
T supply
Expansion Tank

Figure 3. Set-up for thermal efficiency and standby loss test for storage water heaters, storage-type instantaneous water heaters, and unfired hot water storage tanks with horizontal connections

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2.3. *Thermocouples for Measurement of Mean Tank Temperature.* For the standby loss test, install temperature-sensing means inside the tank for measurement of mean tank temperature according to the instructions in section f of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Calculate the mean tank temperature as the average of the six installed temperature-sensing means.

2.4. *Piping Insulation.* Insulate all water piping external to the water heater jacket, including heat traps and piping that are installed by the manufacturer or shipped with the unit, for at least 4 ft of piping length from the connection at the appliance with material having an R-value not less than 4 °F·ft²·h/Btu. Ensure that the insulation does not contact any appliance surface except at the location where the pipe connections penetrate the appliance jacket.

2.5. *Temperature and Pressure Relief Valve Insulation.* If the manufacturer has not provided a temperature and pressure relief valve, one shall be installed and insulated as specified in section 2.4 of this appendix.

2.6. *Vent Requirements.* Follow the requirements for venting arrangements specified in section c of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105).

2.7. *Energy Consumption.* Install equipment that determines, within ± 1 percent:

2.7.1. The quantity and rate of fuel consumed.

2.7.2. The quantity of electricity consumed by factory-supplied water heater components, and of the test loop recirculating pump, if used.

3. *Test Conditions*

3.1. *Water Supply.* Follow the following provisions regarding the water supply to the water heater:

3.1.1. The pressure of the water supply must be maintained between 40 psi and the maximum pressure specified by the manufacturer of the unit being tested. If the maximum water pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default maximum value of 150 psi is to be used. The accuracy of the pressure-measuring devices must be ± 1.0 pounds per square inch (psi).

3.1.2. Isolate the water heater using a shutoff valve in the supply line with an expansion tank installed in the supply line downstream of the shutoff valve. There must be no shutoff means between the expansion tank and the appliance inlet.

3.1.3. During conduct of the thermal efficiency test, the temperature of the supply water must be maintained at 70 °F ± 2 °F.

3.2. *Gas Supply Pressure for Gas-Fired Equipment.* The outlet pressure of the gas appliance pressure regulator must be within the range specified by the manufacturer. If the allowable range of gas supply pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then the outlet pressure of the gas appliance regulator must be within the default range of 4.5 inches water column (in. w.c.) to 10.5 in. w.c. for natural gas-powered units or 11 in. w.c. to 13 in. w.c. for propane-powered units. Obtain the higher heating value of the gas burned.

3.3. *Ambient Room Temperature.* While setting the tank thermostats and verifying steady-state operation (prior to the thermal efficiency test), between the first and second cut-outs prior to the standby loss test, and during the soak-in period, thermal efficiency test, and standby loss test, maintain the ambient room temperature at 75 °F ± 5 °F at all times. Measure the ambient room temperature at 30-second intervals during these periods. Measure the ambient room temperature at the vertical mid-point of the water heater and approximately 2 feet from the water heater jacket. Shield the sensor against radiation. Calculate the average ambient room temperature separately for the soak-in period, thermal efficiency test, and standby loss test. During the soak-in period and thermal efficiency and standby loss tests, the ambient room temperature must not vary by more than ±2.0 °F at any reading from the average ambient room temperature.

3.4. *Test Air Temperature.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency and standby loss tests, the test air temperature must not vary by more than ± 5 °F from the ambient room temperature at any reading. Measure the test air temperature at 30-second intervals during these periods and at a location within two feet of the air inlet of the water heater. For units with multiple air inlets, measure the test air temperature at each air inlet, and maintain the specified tolerance on deviation from the ambient room temperature at each air inlet. For CWH equipment without a specific air inlet, measure the test air temperature within two feet of a location on the water heater where combustion air is drawn.

3.5. *Ambient Humidity.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency and standby loss tests, maintain the ambient relative humidity of the test room at 60 percent ± 5 percent. Measure the ambient relative humidity at 30-second intervals during these periods. The ambient relative humidity must be measured at the same location as the test air temperature. For units with multiple air inlets, measure the ambient relative humidity at each air inlet, and maintain 60 percent ± 5 percent relative humidity at each air inlet.

3.6. *Maximum Air Draft.* During the soak-in period, thermal efficiency test, and standby loss test, the water heater must be located in an area protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement. Prior to beginning the soak-in period, thermal efficiency test, and standby loss test, measure the air draft within three feet of the jacket of the water heater to ensure this condition is met. Ensure that no other changes that would increase the air draft are made to the test set up or conditions during the conduct of the tests.

3.7. *Setting the Tank Thermostat.* Before starting the required soak-in period, the thermostat setting must first be obtained by starting with the water in the system at 70 °F ± 2 °F. The thermostat must then be set so that the maximum outlet water temperature, after the thermostat reduces the fuel supply to a minimum, is 140 °F ± 5 °F.

3.8. *Additional Requirements for Oil-Fired Equipment.*

3.8.1. *Venting Requirements.* Connect a vertical length of flue pipe to the flue gas outlet of sufficient height so as to meet the minimum draft specified by the manufacturer.

3.8.2. *Oil Supply.* Adjust the burner rate so that the following conditions are met:

3.8.2.1. The CO_2 reading is within the range specified by the manufacturer;

3.8.2.2. The fuel pump pressure is within ± 10 percent of manufacturer's specifications;

3.8.2.3. If either the fuel pump pressure or range for CO_2 reading are not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default value of 100 psig is to be used for fuel pump pressure, and a default range of 9–12 percent is to be used for CO_2 reading; and

3.8.2.4. Smoke in the flue does not exceed No. 1 smoke as measured by the procedure in ASTM D2156–09 (incorporated by reference, see § 431.105). To determine the smoke spot number, connect the smoke measuring device to an open-ended tube. This tube must project into the flue ¼ to ½ of the pipe diameter.

3.8.2.5. For the thermal efficiency test, measure the CO_2 reading and determine the smoke spot number after steady-state operation has been obtained as determined by no variation of outlet water temperature in excess of 2 °F over a 3-minute period, but before beginning measurements for the thermal efficiency test. For the standby loss test, measure the CO_2 reading and determine the smoke spot number after the first cut-out before beginning measurements for the standby loss test. However, measurement of the CO_2 reading and conduct of the smoke spot test are not required prior to beginning an efficiency test (*i.e.*, thermal efficiency or standby loss) if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test.

3.9. *Data Collection Intervals.* Follow the data recording intervals specified in the following sections.

3.9.1. *Soak-In Period.* Measure the air draft, in ft/min, before beginning the soak-in period. Measure the ambient room temperature, in °F, every 30 seconds during the soak-in period.

3.9.2. *Thermal Efficiency Test.* Follow the data recording intervals specified in Table 3.1 of this section.

TABLE 3.1—DATA TO BE RECORDED BEFORE AND DURING THE THERMAL EFFICIENCY TEST

Item recorded	Before test	Every 30 seconds[1]	Every 10 minutes
Gas outlet pressure, in w.c.	X		
Fuel higher heating value, Btu/ft^3 (gas) or Btu/lb (oil)	X		
Oil pump pressure, psig (oil only)	X		
CO$_2$ reading, % (oil only)	X[1]		
Oil smoke spot reading (oil only)	X[2]		
Air draft, ft/min	X		
Time, minutes/seconds		X	
Fuel weight or volume, lb (oil) or ft^3 (gas)			X[3]
Supply water temperature, °F		X	
Outlet water temperature, °F		X	
Ambient room temperature, °F		X	
Test air temperature, °F		X	
Ambient relative humidity, %		X	

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

[2] The smoke spot test and CO$_2$ reading are not required prior to beginning the thermal efficiency test if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously-run efficiency test (*i.e.*, thermal efficiency or standby loss).

[3] Fuel and electricity consumption over the course of the entire test must be measured and used in calculation of thermal efficiency.

3.9.3. *Standby Loss Test.* Follow the data recording intervals specified in Table 3.2 of this section. Additionally, the fuel and electricity consumption over the course of the entire test must be measured and used in calculation of standby loss.

TABLE 3.2—DATA TO BE RECORDED BEFORE AND DURING THE STANDBY LOSS TEST

Item recorded	Before test	Every 30 seconds[1]
Gas outlet pressure, in w.c.	X	
Fuel higher heating value, Btu/ft^3 (gas) or Btu/lb (oil)	X	
Oil pump pressure, psig (oil only)	X	
CO$_2$ reading, % (oil only)	X[2]	
Oil smoke spot reading (oil only)	X[2]	
Air draft, ft/min	X	
Time, minutes/seconds		X
Mean tank temperature, °F		X
Ambient room temperature, °F		X
Test air temperature, °F		X
Ambient relative humidity, %		X

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

[2] The smoke spot test and CO$_2$ reading are not required prior to beginning the standby loss test if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously-run efficiency test (*i.e.*, thermal efficiency or standby loss).

4. *Determination of Storage Volume.* Determine the storage volume by subtracting the tare weight—measured while the system is dry and empty—from the weight of the system when filled with water and dividing the resulting net weight of water by the density of water at the measured water temperature.

5. *Soak-In Period.* Prior to conducting a thermal efficiency test or standby loss test, a soak-in period must occur, in which the water heater must sit without any draws taking place for at least 12 hours. Begin the soak-in period after setting the tank thermostats as specified in section 3.7 of this appendix, and maintain these settings throughout the soak-in period. However, a soak-in period is not required prior to beginning an efficiency test (*i.e.*, thermal efficiency or standby loss) if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test.

6. *Thermal Efficiency Test.* Conduct the thermal efficiency test as specified in section j of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105), with the exception of the provision stipulating the data collection intervals for water temperatures. Follow the additional provisions in the following sections:

6.1. *Steady-State Conditions.* Adjust the water flow rate to a constant value such that the following conditions are always satisfied during the test. Once steady-state operation is achieved, as determined by no variation of the outlet water temperature in excess of 2 °F over a 3-minute period, do not change any settings on the water heating equipment until measurements for the thermal efficiency test are finished.

6.1.1. The outlet water temperature must be maintained at 70 °F ± 2 °F above the supply water temperature.

6.1.2. The burner must fire continuously at full firing rate (*i.e.*, no modulation or cut-outs) for the entire duration of the thermal efficiency test.

6.2. *Determination of Fuel Input Rate.* For the thermal efficiency test, record the fuel consumed at 10-minute intervals. Calculate the fuel input rate over each 10-minute period using the equations in section 6.3 of this appendix. The measured fuel input rates for these 10-minute periods must not vary by more than ± 2 percent between any two readings. Determine the overall fuel input rate using the fuel consumption for the entire duration of the thermal efficiency test. Round the overall fuel input rate to the nearest 1,000 Btu/h.

6.3. *Fuel Input Rate Calculation.* To calculate the fuel input rate, use the following equations:

6.3.1. For gas-fired CWH equipment, calculate the fuel input rate using the following equation:

$$Q = \frac{Q_s * C_s * H_{gas}}{t}$$

Where,

Q = Fuel input rate, expressed in Btu/h

Q_s = Total fuel flow as metered, ft^3

C_s = Correction applied to the heating value of a gas H_{gas}, when it is metered at temperature and/or pressure conditions other than the standard conditions for which the value of H_{gas} is based
H_{gas} = Higher heating value of a gas, Btu/ft^3
t = Duration of measurement of fuel consumption

6.3.2. For oil-fired CWH equipment, calculate the fuel input rate using the following equation:

$$Q = \frac{Q_s * H_{oil}}{t}$$

Where,
Q = Fuel input rate, expressed in Btu/h
Q_s = Total weight of fuel, lb
H_{oil} = Higher heating value of oil, Btu/lb
t = Duration of measurement of fuel consumption

7. Standby Loss Test

7.1. Begin fuel flow to the main burner(s) and put the appliance into operation.

7.2. After the first cut-out, allow the water heater to remain in standby mode. At this point, do not change any settings on the water heating equipment until measurements for the standby loss test are finished.

7.3. At the second cut-out, record the time and ambient room temperature, and begin measuring the fuel and electric consumption. Record the initial mean tank temperature.

7.4. The duration of the test must be until the first cut-out that occurs after 24 hours or 48 hours, whichever comes first.

7.5. Immediately after conclusion of the test, record the total fuel flow and electrical energy consumption, the final ambient room temperature, the duration of the standby loss test, and the final mean tank temperature. Calculate the average of the recorded values of the mean tank temperature and of the ambient air temperatures taken at each measurement interval, including the initial and final values.

7.6. *Standby Loss Calculation.* To calculate the standby loss, follow the steps given below:

7.6.1. The standby loss expressed as a percentage (per hour) of the heat content of the stored water above room temperature must be calculated using the following equation for gas-fired equipment:

$$S = \frac{E_c + (C_s)(Q_s)(H) - \left(\frac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

And using the following equation for oil-fired equipment:

$$S = \frac{E_c + (Q_s)(H) - \left(\frac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

Where,
ΔT_3 = Average value of the mean tank temperature minus the average value of the ambient room temperature, expressed in °F
ΔT_4 = Final mean tank temperature measured at the end of the test minus the initial mean tank temperature measured at the start of the test, expressed in °F
k = 8.25 Btu/gallon·°F, the nominal specific heat of water
V_a = Volume of water contained in the water heater in gallons measured in accordance with section 4 of this appendix
E_t = Thermal efficiency of the water heater measured in accordance with this appendix, expressed in %
E_c = Electrical energy consumed by the water heater during the duration of the test in Btu
t = Total duration of the test in hours
C_s= Correction applied to the heating value of a gas H, when it is metered at temperature and/or pressure conditions other than the standard conditions for which the value of H is based.
Q_s = Total fuel flow as metered, expressed in ft^3 (gas) or lb (oil)
H = Higher heating value of fuel, expressed in Btu/ft^3 (gas) or Btu/lb (oil)
S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the heat content of the stored water above room temperature

7.6.2. The standby loss expressed in Btu per hour must be calculated as follows: SL (Btu per hour) = S (% per hour) × 8.25 (Btu/gal-°F) × Measured Volume (gal) × 70 (°F).

■ 13. Add appendix B to subpart G of part 431 to read as follows:

Appendix B to Subpart G of Part 431—Uniform Test Method for the Measurement of Standby Loss of Electric Storage Water Heaters and Storage-Type Instantaneous Water Heaters

Note: Prior to (*date 360 days after date of publication of the test procedure final rule in the* ***Federal Register***), manufacturers must make any representations with respect to the energy use or efficiency of the subject commercial water heating equipment in accordance with the results of testing pursuant to this appendix or the procedures in 10 CFR 431.106 that were in place on January 1, 2016. On and after (*date 360 days after date of publication of the test procedure final rule in the* ***Federal Register***), manufacturers must make any representations with respect to energy use or efficiency of electric storage water heaters and storage-type instantaneous water heaters in accordance with the results of testing pursuant to this appendix to demonstrate compliance with the energy conservation standards at 10 CFR 431.110.

1. General

Determine the standby loss in accordance with the following sections of this appendix. Certain sections reference sections of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Where the instructions contained in the sections below conflict with instructions in Annex E.1 of ANSI Z21.10.3–2015, the instructions contained herein control.

2. Test Set-Up

2.1. *Placement of Water Heater.* A water heater for installation on combustible floors is to be placed on a ¾-inch plywood platform supported by three 2 × 4-inch runners. If the water heater is for installation on noncombustible floors, suitable noncombustible material is to be placed on the platform. When the use of the platform for a large water heater is not practical, the water heater may be placed on any suitable flooring. A wall-mounted water heater is to be mounted to a simulated wall section.

2.2. *Heat Trap and Thermocouple Installation.* Inlet and outlet piping must be turned vertically downward from the connections on a tank-type water heater so as to form heat traps. Thermocouples for measuring supply and outlet water temperatures must be installed upstream of the inlet heat trap piping and downstream of the outlet heat trap, respectively, in accordance with Figure 1, 2, or 3 (as applicable) presented in section 2.2 of appendix A to this subpart. The total vertical (upward and downward) piping between the thermocouples sensing location and the connection port must be 24 inches. For water heaters with vertical connections, the 24 inches of total vertical piping length is divided into 6 inches of vertical piping upstream from the turn for the heat trap and 18 inches downstream from the turn for the heat trap. For water heaters that have vertical connections (top and bottom), the total horizontal piping between the connection port and the thermocouple sensing location must be equal to the distance between the water heater connection port and the edge of the water heater plus 2 inches. For water heaters that have horizontal connections, the total horizontal piping between the water heater connection port and the temperature sensing location, must be equal to 6 inches. The water heater must meet the requirements shown in either Figure 1, 2, or 3 (as applicable) at all times during the conduct of the standby loss test. Any factory-supplied heat traps must be installed per the installation instructions while ensuring the requirements in Figure 1, 2, or 3 are met. All dimensions specified in Figure 1, 2, and 3 and in this section are measured from the outer surface of the pipes and water heater outer casing (as applicable).

2.3. *Thermocouples for Measurement of Mean Tank Temperature.* Install temperature-sensing means inside the tank for measurement of mean tank temperature according to the instructions in section f of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Calculate the mean tank temperature as the average of the six installed temperature-sensing means.

2.4. *Piping Insulation.* Insulate all water piping external to the water heater jacket, including heat traps and piping that are installed by the manufacturer or shipped with the unit, for at least 4 ft of piping length from the connection at the appliance with material having an R-value not less than 4 °F·ft^{2}·h/Btu. Ensure that the insulation does not contact any appliance surface except at the location where the pipe connections penetrate the appliance jacket.

2.5. *Temperature and Pressure Relief Valve Insulation.* If the manufacturer has not provided a temperature and pressure relief valve, one shall be installed and insulated as specified in section 2.4 of this appendix.

2.6. *Energy Consumption.* Install equipment that determines, within ± 1 percent, the quantity of electricity consumed by factory-supplied water heater components, and of the test loop recirculating pump, if used.

3. Test Conditions

3.1. *Water Supply.* Follow the following provisions regarding the water supply to the water heater:

3.1.1. The pressure of the water supply must be maintained between 40 psi and the maximum pressure specified by the manufacturer of the unit being tested. If the maximum water pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default maximum value of 150 psi is to be used. The accuracy of the pressure-measuring devices must be ± 1.0 pounds per square inch (psi).

3.1.2. Isolate the water heater using a shutoff valve in the supply line with an expansion tank installed in the supply line downstream of the shutoff valve. There must be no shutoff means between the expansion tank and the appliance inlet.

3.2. *Electrical Supply.* Maintain the electrical supply voltage to within ± 5 percent of the center of the voltage range specified on the water heater nameplate.

3.3. *Ambient Room Temperature.* While setting the tank thermostats, between the first and second cut-outs prior to the standby loss test, and during the soak-in period and standby loss test, maintain the ambient room temperature at 75 °F ± 5 °F at all times. Measure the ambient room temperature at 30-second intervals during these periods. Measure the ambient room temperature at the vertical mid-point of the water heater and approximately 2 feet from the water heater jacket. Shield the sensor against radiation. Calculate the average ambient room temperature separately for the soak-in period and the standby loss test. During the soak-in period and standby loss test, the room temperature must not vary more than ± 2.0 °F at any reading from the average ambient room temperature.

3.4. *Maximum Air Draft.* During the soak-in period and standby loss test, the water heater must be located in an area protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement. Prior to beginning the soak-in period and standby loss test, measure the air draft within three feet of the jacket of the water heater to ensure this condition is met. Ensure that no other changes that would increase the air draft are made to the test set up or conditions during the conduct of the tests.

3.5. *Setting the Tank Thermostats.* Before starting the required soak-in period, the thermostat setting(s) must first be obtained as explained in the following sections.

3.5.1. For water heaters with a single thermostat, the thermostat setting must be obtained by starting with the water in the system at 70 °F ± 2 °F. The thermostat must be set so that the maximum mean tank temperature after cut-out is 140 °F ± 5 °F.

3.5.2. For water heaters with multiple adjustable thermostats, set the topmost thermostat first to yield a maximum mean water temperature after cut-out of 140 °F ± 5 °F. Immediately after setting the top thermostat, sequentially set the lower thermostat(s) from highest to lowest so that each yields a maximum mean water temperature after cut-out equal to 140 °F ± 5 °F. When setting each thermostat (with the exception of the bottommost thermostat), calculate the mean tank temperature using only the temperature readings measured at locations higher in the tank than the heating element corresponding to the thermostat being set. While setting each thermostat, all thermostats below the thermostat being tested must be turned off so that no elements below the thermostat being tested are in operation. When setting the bottommost thermostat, calculate the mean tank temperature using all tank thermocouples. After cut-out by all thermostats in the water heater, the maximum mean tank temperature must be 140 °F ± 5 °F.

3.6. *Data Collection Intervals.* Follow the data recording intervals specified in the following sections.

3.6.1. *Soak-In Period.* Measure the air draft, in ft/min, before beginning the soak-in period. Measure the ambient room temperature, in °F, every 30 seconds during the soak-in period.

3.6.2. *Standby Loss Test.* Follow the data recording intervals specified in Table 3.1 of this section. Additionally, the electricity consumption over the course of the entire test must be measured and used in calculation of standby loss.

TABLE 3.1—DATA TO BE RECORDED BEFORE AND DURING THE STANDBY LOSS TEST

Item recorded	Before test	Every 30 seconds[1]
Air draft, ft/min	X	
Time, minutes/seconds		X
Mean tank temperature, °F		X
Ambient room temperature, °F		X

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

4. *Determination of Storage Volume.* Determine the storage volume by subtracting the tare weight—measured while the system is dry and empty—from the weight of the system when filled with water and dividing the resulting net weight of water by the density of water at the measured water temperature.

5. *Soak-In Period.* Prior to conducting a standby loss test, a soak-in period must occur, in which the water heater must sit without any draws taking place for at least 12 hours. Begin the soak-in period after setting the tank thermostats as specified in section 3.5 of this appendix, and maintain these settings throughout the soak-in period.

6. Standby Loss Test

6.1. Initiate normal operation of the water heater.

6.2. After the first cut-out, allow the water heater to remain in standby mode. At this point, do not change any settings on the water heating equipment until measurements for the standby loss test are finished.

6.3. At the second cut-out, record the time and ambient room temperature, and begin measuring the electric consumption. Record the initial mean tank temperature.

6.4. The duration of the test must be until the first cut-out that occurs after 24 hours or 48 hours, whichever comes first.

6.5. Immediately after conclusion of the test, record the total electrical energy consumption, the final ambient room temperature, the duration of the standby loss test, and the final mean tank temperature. Calculate the average of the recorded values of the mean tank temperature and of the ambient air temperatures taken at each measurement interval, including the initial and final values.

6.6. *Standby Loss Calculation.* To calculate the standby loss, follow the steps given below:

6.6.1. The standby loss expressed as a percentage (per hour) of the heat content of the stored water above room temperature must be calculated using the following equation:

$$S = \frac{E_c - \left(\frac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

Where,

ΔT_3 = Average value of the mean tank temperature minus the average value of the ambient room temperature, expressed in °F
ΔT_4 = Final mean tank temperature measured at the end of the test minus the initial mean tank temperature measured at the start of the test, expressed in °F
k = 8.25 Btu/gallon·°F, the nominal specific heat of water
V_a = Volume of water contained in the water heater in gallons measured in accordance with section 4 of this appendix
E_t = Thermal efficiency—assume 98 percent for electric water heaters with immersed heating elements
E_c = Electrical energy consumed by the water heater during the duration of the test in Btu
t = Total duration of the test in hours
S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the heat content of the stored water above room temperature

■ 14. Add appendix C to subpart G of part 431 to read as follows:

Appendix C to Subpart G of Part 431—Uniform Test Method for the Measurement of Thermal Efficiency and Standby Loss of Gas-Fired and Oil-Fired Instantaneous Water Heaters and Hot Water Supply Boilers (Other Than Flow-Activated Instantaneous Water Heaters and Storage-Type Instantaneous Water Heaters)

Note: Prior to (*date 360 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to the energy use or efficiency of the subject commercial water heating equipment in accordance with the results of testing pursuant to this appendix or the procedures in 10 CFR 431.106 that were in place on January 1, 2016. On and after (*date 360 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to energy use or efficiency of gas-fired and oil-fired instantaneous water heaters and hot water supply boilers (other than flow-activated instantaneous water heaters and storage-type instantaneous water heaters) in accordance with the results of testing pursuant to this appendix to demonstrate compliance with the energy conservation standards at 10 CFR 431.110.

1. General

Determine the thermal efficiency and standby loss (as applicable) in accordance with the following sections of this appendix. Certain sections reference sections of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Where the instructions contained in the sections below conflict with instructions in Annex E.1 of ANSI Z21.10.3–2015, the instructions contained herein control.

2. Test Set-Up

2.1. *Placement of Water Heater.* A water heater for installation on combustible floors is to be placed on a ¾-inch plywood platform supported by three 2 x 4-inch runners. If the water heater is for installation on noncombustible floors, suitable noncombustible material is to be placed on the platform. When the use of the platform for a large water heater is not practical, the water heater may be placed on any suitable flooring. A wall-mounted water heater is to be mounted to a simulated wall section.

2.2. *Test Configuration.* Set up the instantaneous water heater or hot water supply boiler in accordance with Figure 4 of this section.

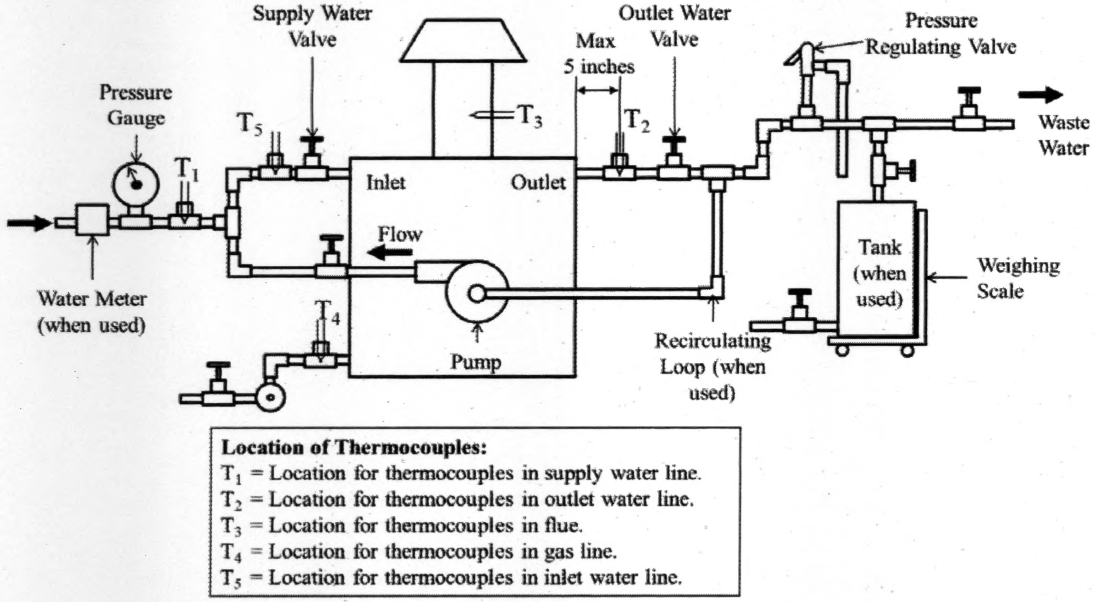
Supply Water Valve
Outlet Water Valve
Max 5 inches
Pressure Regulating Valve
Pressure Gauge
T_5
T_3
T_2
T_1
Waste Water
Inlet
Outlet
Flow
Tank (when used)
Weighing Scale
Water Meter (when used)
T_4
Pump
Recirculating Loop (when used)
Location of Thermocouples:
T_1 = Location for thermocouples in supply water line.
T_2 = Location for thermocouples in outlet water line.
T_3 = Location for thermocouples in flue.
T_4 = Location for thermocouples in gas line.
T_5 = Location for thermocouples in inlet water line.

Figure 4. Set-up for thermal efficiency and standby loss test of instantaneous water heaters (other than storage-type instantaneous water heaters) and hot water supply boilers

2.2.1. If the instantaneous water heater or hot water supply boiler does not have any external piping, install a supply water valve within 5 inches of the water heater jacket, and install an outlet water valve within 10 inches of the water heater jacket. If the instantaneous water heater or hot water supply boiler includes external piping assembled at the manufacturer's premises prior to shipment, install water valves in the supply and outlet piping (as applicable) within 5 inches of the end of the piping supplied with the unit.

2.2.2. If the water heater is not able to achieve an outlet water temperature of 70 °F ± 2 °F above the supply water temperature at a constant maximum fuel input rate, a recirculating loop with pump as shown in Figure 4 in section 2.2 of this appendix must be used.

2.2.2.1. If a recirculating loop with a pump is used then ensure that the inlet water temperature labeled as T_5 in Figure 4 in section 2.2 of this appendix, is greater than or equal to 70 °F and less than or equal to 120 °F at all times during the thermal efficiency test and while achieving steady-state conditions prior to the standby loss test.

2.3. *Installation of Temperature-Sensing Means.* The temperature-sensing means must be installed in a manner such that the tip or the junction of the temperature sensing probe is in the water; less than or equal to 5 inches away from the outer casing of the equipment being tested; in the line of the central axis of the water pipe; and enclosed in a radiation protection shield. Figure 4 in section 2.2 of this appendix shows the placement of the outlet water temperature-sensing instrument at a maximum distance of 5 inches away from the surface of the jacket of the equipment being tested. For water heaters with multiple outlet water connections leaving the water heater jacket, temperature-sensing means must be installed for each outlet water connection leaving the water heater in accordance with the provisions in this section.

2.4. *Piping Insulation.* Insulate all water piping external to the water heater jacket, including piping that are installed by the manufacturer or shipped with the unit, for at least 4 ft of piping length from the connection at the appliance with material having an R-value not less than 4 °F·ft²·h/Btu. Ensure that the insulation does not contact any appliance surface except at the location where the pipe connections penetrate the appliance jacket.

2.5. *Temperature and Pressure Relief Valve Insulation.* If the manufacturer has not provided a temperature and pressure relief valve, one shall be installed and insulated as specified in section 2.4 of this appendix.

2.6. *Vent Requirements.* Follow the requirements for venting arrangements specified in section c of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105).

2.7. *Energy Consumption.* Install equipment that determines, within ±1 percent:

2.7.1. The quantity and rate of fuel consumed.

2.7.2. The quantity of electricity consumed by factory-supplied water heater components, and of the test loop recirculating pump, if used.

3. Test Conditions

3.1. *Water Supply.* Follow the following provisions regarding the water supply to the water heater:

3.1.1. The pressure of the water supply must be maintained between 40 psi and the maximum pressure specified by the manufacturer of the unit being tested. If the maximum water pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default maximum value of 150 psi is to be used. The accuracy of the pressure-measuring devices must be ±1.0 pounds per square inch (psi).

3.1.2. During conduct of the thermal efficiency test, the temperature of the supply water must be maintained at 70 °F ± 2 °F.

3.2. *Gas Supply Pressure for Gas-Fired Equipment.* The outlet pressure of the gas appliance pressure regulator must be within the range specified by the manufacturer. If the allowable range of gas supply pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then the outlet pressure of the gas appliance regulator must be within the default range of 4.5 inches of water column (in. w.c.) to 10.5 in. w.c. for natural gas-powered units, or 11 in. w.c. to 13 in. w.c. for propane-powered units. Obtain the higher heating value of the gas burned.

3.3. *Ambient Room Temperature.* While verifying steady-state operation (prior to the thermal efficiency test), between the first and second cut-outs prior to the standby loss test (as applicable), and during the thermal efficiency and standby loss tests (as applicable), maintain the ambient room temperature at 75 °F ± 5 °F at all times. Measure the ambient room temperature at 30-second intervals during these periods. Measure the ambient room temperature at the vertical mid-point of the water heater and approximately 2 feet from the water heater jacket. Shield the sensor against radiation. Calculate the average ambient room temperature separately for the thermal efficiency and standby loss tests (as applicable). The ambient room temperature must not vary by more than ±2.0 °F at any reading from the average ambient room temperature.

3.4. *Test Air Temperature.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency and standby loss tests (as applicable), the test air temperature must not vary by more than ±5 °F from the ambient room temperature at any reading. Measure the test air temperature at 30-second intervals during these periods and at a location within two feet of the air inlet of the water heater. For units with multiple air inlets, measure the test air temperature at each air inlet, and maintain the specified tolerance on deviation from the ambient room temperature at each air inlet. For CWH equipment without a specific air inlet, measure the test air temperature within two feet of a location on the water heater where combustion air is drawn.

3.5. *Ambient Humidity.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency and standby loss tests (as applicable), maintain the ambient relative humidity of the test room at 60 percent ±5 percent. Measure the ambient relative humidity at 30-second intervals during these periods. The ambient relative humidity must be measured at the same location as the test air temperature. For units with multiple air inlets, measure the ambient relative humidity at each air inlet, and maintain 60 percent ±5 percent relative humidity at each air inlet.

3.6. *Maximum Air Draft.* During the thermal efficiency and standby loss tests (as applicable), the water heater must be located in an area protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement. Prior to beginning the thermal efficiency and standby loss tests, measure the air draft within three feet of the jacket of the water heater to ensure this condition is met. Ensure that no other changes that would increase the air draft are made to the test set up or conditions during the conduct of the tests.

3.7. *Setting the Thermostat.* Before beginning the thermal efficiency or standby loss tests, the thermostat setting must first be obtained by starting with the water in the system at 70 °F ± 2 °F. The thermostat must then be set so that the maximum outlet water temperature, after the thermostat reduces the fuel supply to a minimum, is 140 °F ± 5 °F.

3.8. *Additional Conditions for Units With Multiple Water Connections.* For units with multiple water connections leaving the water heater, use the following provisions:

3.8.1. The outlet water temperature measured from each connection leaving the water heater, must be maintained at 70 °F ± 2 °F above the supply water temperature, and must not differ from any other outlet water connection by more than 2 °F during the thermal efficiency test.

3.8.2. To calculate the outlet water temperature representative for the entire unit, calculate the average of the outlet water temperature measured at each connection leaving the water heater jacket. This average must be taken for each reading recorded by the data acquisition unit. The outlet water temperature obtained for each reading must be used for carrying out all calculations for the thermal efficiency and standby loss tests.

3.9. Additional Requirements for Oil-Fired Equipment.

3.9.1. *Venting Requirements.* Connect a vertical length of flue pipe to the flue gas outlet of sufficient height so as to meet the minimum draft specified by the manufacturer.

3.9.2. *Oil Supply.* Adjust the burner rate so that the following conditions are met:

3.9.2.1. The CO_2 reading is within the range specified by the manufacturer;

3.9.2.2. The fuel pump pressure is within ±10 percent of manufacturer's specifications;

3.9.2.3. If either the fuel pump pressure or range for CO_2 reading are not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default value of 100 psig is to be used for fuel pump pressure, and a default range of 9–12 percent is to be used for CO_2 reading; and

3.9.2.4. Smoke in the flue does not exceed No. 1 smoke as measured by the procedure in ASTM D2156–09 (incorporated by reference, see § 431.105). To determine the smoke spot number, the smoke measuring device shall be connected to an open-ended tube. This tube must project into the flue ¼ to ½ of the pipe diameter.

3.9.2.5. For the thermal efficiency test, measure the CO_2 reading and determine the smoke spot number after steady-state operation has been obtained as determined by no variation of outlet water temperature in excess of 2 °F over a 3-minute period, but before beginning measurements for the thermal efficiency test. For the standby loss test, measure the CO_2 reading and determine the smoke spot number after the first cut-out before beginning measurements for the standby loss test. However, measurement of the CO_2 reading and conduct of the smoke spot test are not required prior to beginning an efficiency test (*i.e.*, thermal efficiency or standby loss) if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run efficiency test.

3.10. *Data Collection Intervals.* Follow the data recording intervals specified in the following sections.

3.10.1. *Thermal Efficiency Test.* Follow the data recording intervals specified in Table 3.1 of this section.

TABLE 3.1—DATA TO BE RECORDED BEFORE AND DURING THE THERMAL EFFICIENCY TEST

Item recorded	Before test	Every 30 seconds[1]	Every 10 minutes
Gas outlet pressure, in w.c.	X		
Fuel higher heating value, Btu/ft^3 (gas) or Btu/lb (oil)	X		
Oil pump pressure, psig (oil only)	X		
CO_2 reading, % (oil only)	X[2]		
Oil smoke spot reading (oil only)	X[2]		
Air draft, ft/min	X		
Time, minutes/seconds		X	
Fuel weight or volume, lb (oil) or ft^3 (gas)			X[3]
Supply water temperature, °F		X	
Outlet water temperature, °F		X	
Ambient room temperature, °F		X	
Test air temperature, °F		X	
Ambient relative humidity, %		X	

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

[2] The smoke spot test and CO_2 reading are not required prior to beginning the thermal efficiency test if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously-run efficiency test (*i.e.*, thermal efficiency or standby loss).

[3] Fuel and electricity consumption over the course of the entire test must be measured and used in calculation of thermal efficiency.

3.10.2. *Standby Loss Test.* Follow the data recording intervals specified in Table 3.2 of this section. Additionally, the fuel and electricity consumption over the course of the entire test must be measured and used in calculation of standby loss.

TABLE 3.2—DATA TO BE RECORDED BEFORE AND DURING THE STANDBY LOSS TEST

Item recorded	Before test	Every 30 seconds[1]
Gas outlet pressure, in w.c.	X	
Fuel higher heating value, Btu/ft^3 (gas) or Btu/lb (oil)	X	
Oil pump pressure, psig (oil only)	X	
CO_2 reading, % (oil only)	X[2]	
Oil smoke spot reading (oil only)	X[2]	
Air draft, ft/min	X	
Time, minutes/seconds		X
Outlet water temperature, °F		X
Ambient room temperature, °F		X
Test air temperature, °F		X
Ambient relative humidity, %		X

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

[2] The smoke spot test and CO_2 reading are not required prior to beginning the thermal efficiency test if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously-run efficiency test (*i.e.*, thermal efficiency or standby loss).

4. *Determination of Storage Volume.* Determine the storage volume by subtracting the tare weight—measured while the system is dry and empty—from the weight of the system when filled with water and dividing the resulting net weight of water by the density of water at the measured water temperature.

5. *Thermal Efficiency Test.* Conduct the thermal efficiency test as specified in section j of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105), with the exception of the provision stipulating the data collection intervals for water temperatures. Follow the additional provisions in the following sections:

5.1. *Steady-State Conditions.* Adjust the water flow rate to a constant value such that the following conditions are always satisfied during the test. Once steady-state operation is achieved, as determined by no variation of the outlet water temperature in excess of 2 °F over a 3-minute period, do not change any settings on the water heating equipment until measurements for the thermal efficiency test are finished.

5.1.1. The outlet water temperature must be maintained at 70 °F ± 2 °F above the supply water temperature.

5.1.2. The burner must fire continuously at full firing rate (*i.e.*, no modulation or cut-outs) for the entire duration of the thermal efficiency test.

5.2. *Determination of Fuel Input Rate.* For the thermal efficiency test, record the fuel consumption at 10-minute intervals. Calculate the fuel input rate for each 10-minute period using the equations in section 5.3 of this appendix. The measured fuel input rates for these 10-minute periods must not vary by more than ± 2 percent between any two readings. Determine the overall fuel input rate using the fuel consumption for the entire duration of the thermal efficiency test. Round the overall fuel input rate to the nearest 1,000 Btu/h.

5.3. *Fuel Input Rate Calculation.* To calculate the fuel input rate, use the following equations:

5.3.1. For gas-fired CWH equipment, calculate the fuel input rate using the following equation:

$$Q = \frac{Q_s * C_s * H_{gas}}{t}$$

Where,

Q = Fuel input rate, expressed in Btu/h
Q_s = Total fuel flow as metered, ft^3
C_s = Correction applied to the heating value of a gas H_{gas}, when it is metered at temperature and/or pressure conditions other than the standard conditions for which the value of H_{gas} is based
H_{gas} = Higher heating value of a gas, Btu/ft^3
t = Duration of measurement of fuel consumption

5.3.2. For oil-fired CWH equipment, calculate the fuel input rate using the following equation:

$$Q = \frac{Q_s * H_{oil}}{t}$$

Where,

Q = Fuel input rate, expressed in Btu/h
Q_s = Total weight of fuel, lb
H_{oil} = Higher heating value of oil, Btu/lb
t = Duration of measurement of fuel consumption

6. Standby Loss Test

6.1. Begin fuel flow to the main burner(s) and put the appliance into operation. Prior to beginning the standby loss test, the outlet water temperature must become constant, as indicated by no variation in excess of 2 °F over a 3-minute period, unless no settings on the water heater were changed and the water heater has not been turned off since the completion of the thermal efficiency test.

6.2. After ensuring the outlet water temperature is constant or if no settings on the water heater have been changed and the water heater has not been turned off since completion of the thermal efficiency test, turn off the supply water valve(s), the outlet water valve(s) (installed as per the provisions in section 2.2 of this appendix), and the water pump simultaneously and ensure that there is no flow of water through the water heater.

6.3. After the first cut-out, allow the water heater to remain in standby mode. At this point, do not change any settings on the water heating equipment until measurements for the standby loss test are finished.

6.4. At the second cut-out, record the time and ambient room temperature, and begin measuring the fuel and electric consumption. Record the initial outlet water temperature.

6.5. The duration of the test must be until the first cut-out that occurs after 24 hours or 48 hours, whichever comes first.

6.6. Immediately after conclusion of the test, record the total fuel flow and electrical energy consumption, the final ambient room temperature, the duration of the standby loss test, and the final outlet water temperature. Calculate the average of the recorded values of the outlet water temperature and of the ambient air temperatures taken at each measurement interval, including the initial and final values.

6.7. *Standby Loss Calculation.* To calculate the standby loss, follow the steps given below:

6.7.1. The standby loss expressed as a percentage (per hour) of the heat content of the stored water above room temperature must be calculated using the following equation for gas-fired equipment:

$$S = \frac{E_c + (C_s)(Q_s)(H) - \left(\frac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

And using the following equation for oil-fired equipment:

$$S = \frac{E_c + (Q_s)(H) - \left(\frac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

Where,

ΔT_3 = Average value of the outlet water temperature minus the average value of the ambient room temperature, expressed in °F

ΔT_4 = Final outlet water temperature measured at the end of the test minus the initial outlet water temperature measured at the start of the test, expressed in °F

k = 8.25 Btu/gallon·°F, the nominal specific heat of water

V_a = Volume of water contained in the water heater in gallons measured in accordance with section 4 of this appendix

E_t = Thermal efficiency of the water heater measured in accordance with this appendix, expressed in %

E_c = Electrical energy consumed by the water heater during the duration of the test in Btu

t = Total duration of the test in hours

C_s = Correction applied to the heating value of a gas H, when it is metered at temperature and/or pressure conditions other than the standard conditions for which the value of H is based.

Q_s = Total fuel flow as metered, expressed in ft^3 (gas) or lb (oil)

H = Higher heating value of gas or oil, expressed in Btu/ft^3 (gas) or Btu/lb (oil)

S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the heat content of the stored water above room temperature

6.7.2. The standby loss expressed in Btu per hour must be calculated as follows: SL (Btu per hour) = S (% per hour) × 8.25 (Btu/gal-°F) × Measured Volume (gal) × 70 (°F).

■ 15. Add appendix D to subpart G of part 431 to read as follows:

Appendix D to Subpart G of Part 431—Uniform Test Method for the Measurement of Standby Loss of Electric Instantaneous Water Heaters (Other Than Flow-Activated Instantaneous Water Heaters and Storage-Type Instantaneous Water Heaters)

Note: Prior to (*date 360 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to the energy use or efficiency of the subject commercial water heating equipment in accordance with the results of testing pursuant to this appendix or the procedures in 10 CFR 431.106 that were in place on January 1, 2016. On and after (*date 360 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to energy use or efficiency of electric instantaneous water heaters (other than flow-activated instantaneous water heaters and storage-type instantaneous water heaters) in accordance with the results of testing pursuant to this appendix to demonstrate compliance with the energy conservation standards at 10 CFR 431.110.

1. General

Determine the standby loss (as applicable) in accordance with the following sections of this appendix. Certain sections reference sections of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Where the instructions contained in the sections below conflict with instructions in Annex E.1 of ANSI Z21.10.3–2015, the instructions contained herein control.

2. Test Set-Up

2.1. *Placement of Water Heater.* A water heater for installation on combustible floors is to be placed on a ¾-inch plywood platform supported by three 2 x 4-inch runners. If the water heater is for installation on noncombustible floors, suitable noncombustible material is to be placed on the platform. When the use of the platform for a large water heater is not practical, the water heater may be placed on any suitable flooring. A wall-mounted water heater is to be mounted to a simulated wall section.

2.2. *Test Configuration.* Set up the water heater in accordance with Figure 4 in section 2.2 of appendix C to this subpart.

2.2.1. If the instantaneous water heater or hot water supply boiler does not have any external piping, install a supply water valve within 5 inches of the water heater jacket, and install an outlet water valve within 10 inches of the water heater jacket. If the instantaneous water heater or hot water supply boiler includes external piping assembled at the manufacturer's premises prior to shipment, install water valves in the supply and outlet piping (as applicable) within 5 inches of the end of the piping supplied with the unit.

2.2.2. If the water heater is not able to achieve an outlet water temperature of 70 °F ± 2 °F above the supply water temperature at a constant maximum fuel (or electricity) input rate, a recirculating loop with pump as shown in Figure 4 in section 2.2 of appendix C to this subpart must be used.

2.2.2.1. If a recirculating loop with a pump is used then ensure that the inlet water temperature labeled as T_5 in Figure 4 in section 2.2 of appendix C to this subpart, is greater than or equal to 70 °F and less than or equal to 120 °F at all times while achieving steady-state conditions prior to the standby loss test.

2.3. *Installation of Temperature-Sensing Means.* The temperature-sensing means must be installed in a manner such that the tip or the junction of the temperature sensing probe is in the water; less than or equal to 5 inches away from the outer casing of the equipment being tested; in the line of the central axis of the water pipe; and enclosed in a radiation protection shield. Figure 4 in section 2.2 of appendix C to this subpart shows the placement of the outlet water temperature-sensing instrument at a maximum distance of 5 inches away from the surface of the jacket of the equipment being tested. For water heaters with multiple outlet water connections leaving the water heater jacket, temperature-sensing means must be installed for each outlet water connection leaving the water heater in accordance with the provisions in this section.

2.4. *Piping Insulation.* Insulate all the water piping external to the water heater jacket, including piping that are installed by the manufacturer or shipped with the unit, for at least 4 ft of piping length from the connection at the appliance with material having an R-value not less than 4 °F·ft^2·h/Btu. Ensure that the insulation does not contact any appliance surface except at the location where the pipe connections penetrate the appliance jacket.

2.5. *Temperature and Pressure Relief Valve Insulation.* If the manufacturer has not provided a temperature and pressure relief valve, one shall be installed and insulated as specified in section 2.4 of this appendix.

2.6. *Energy Consumption.* Install equipment that determines, within ± 1 percent, the quantity of electricity consumed by factory-supplied water heater components, and of the test loop recirculating pump, if used.

3. Test Conditions

3.1. *Water Supply.* Follow the following provisions regarding the water supply to the water heater:

3.1.1. The pressure of the water supply must be maintained between 40 psi and the maximum pressure specified by the manufacturer of the unit being tested. If the maximum water pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default maximum value of 150 psi is to be used. The accuracy of the pressure-measuring devices must be ± 1.0 pounds per square inch (psi).

3.2. *Electrical Supply.* Maintain the electrical supply voltage to within ± 5 percent of the center of the voltage range specified on the water heater nameplate.

3.3. *Ambient Room Temperature.* Between the first and second cut-outs prior to the standby loss test and during the standby loss test, maintain the ambient room temperature at 75 °F ± 5 °F at all times. Measure the ambient room temperature at 30-second intervals during these periods. Measure the ambient room temperature at the vertical mid-point of the water heater and approximately 2 feet from the water heater jacket. Shield the sensor against radiation. Calculate the average ambient room temperature for the standby loss test. The ambient room temperature must not vary more than ± 2.0 °F at any reading from the average ambient room temperature.

3.4. *Maximum Air Draft.* During the standby loss test, the water heater must be located in an area protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement. Prior to beginning the standby loss test, measure the air draft within three feet of the jacket of the water heater to ensure this condition is met. Ensure that no other changes that would increase the air draft are made to the test set up or conditions during the conduct of the tests.

3.5. *Setting the thermostat.* Before beginning the standby loss test, the thermostat setting must first be obtained by starting with the water in the system at 70 °F ± 2 °F. While setting the thermostat, ensure that all heating elements are constantly operating. The thermostat must then be set so that the maximum outlet water temperature after cut-out is 140 °F ± 5 °F.

3.6. *Additional Conditions for Units with Multiple Outlet Water Connections.* For units with multiple outlet water connections leaving the water heater, use the following provisions:

3.6.1. The outlet water temperature measured from each connection leaving the water heater prior to conducting the standby loss test must be maintained at 70 °F ± 2 °F above the supply water temperature, and must not differ from any other outlet water connection by more than 2 °F prior to starting the standby loss test.

3.6.2. To calculate the outlet water temperature representative for the entire unit, calculate the average of the outlet water temperature measured at each connection leaving the water heater jacket. This average must be taken for each reading recorded by the data acquisition unit. The outlet water temperature obtained for each reading must be used for carrying out all calculations for the standby loss test.

3.7. *Data Collection Intervals.* During the standby loss test, follow the data recording intervals specified in Table 3.1 of this section. Also, the electricity consumption over the course of the entire test must be measured and used in calculation of standby loss.

TABLE 3.1—DATA TO BE RECORDED BEFORE AND DURING THE STANDBY LOSS TEST

Item recorded	Before test	Every 30 seconds [1]
Air draft, ft/min	X	
Time, minutes/seconds		X
Outlet water temperature, °F		X
Ambient room temperature, °F		X

Note:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

4. *Determination of Storage Volume.* Determine the storage volume by subtracting the tare weight—measured while the system is dry and empty—from the weight of the system when filled with water and dividing the resulting net weight of water by the density of water at the measured water temperature.

5. Standby Loss Test

5.1. Initiate normal operation of the water heater. Prior to beginning the standby loss test, the outlet water temperature must become constant, as indicated by no variation in excess of 2 °F over a 3-minute period.

5.2. After ensuring the outlet water temperature is constant, turn off the supply water valve(s), the outlet water valve(s) (installed as per the provisions in section 2.2 of this appendix), and the water pump simultaneously and ensure that there is no flow of water through the water heater.

5.3. After the first cut-out, allow the water heater to remain in standby mode. At this point, do not change any settings on the water heating equipment until measurements for the standby loss test are finished.

5.4. At the second cut-out, record the time and ambient room temperature, and begin measuring the electric consumption. Record the initial outlet water temperature.

5.5. The duration of the test must be until the first cut-out that occurs after 24 hours or 48 hours, whichever comes first.

5.6. Immediately after conclusion of the test, record the total electrical energy consumption, the final ambient room temperature, the duration of the standby loss test, and the final outlet water temperature. Calculate the average of the recorded values of the outlet water temperature and of the ambient air temperatures taken at each measurement interval, including the initial and final values.

5.7. *Standby Loss Calculation.* To calculate the standby loss, follow the steps given below:

5.7.1. The standby loss expressed as a percentage (per hour) of the heat content of the stored water above room temperature must be calculated using the following equation:

$$S = \frac{E_c - \left(\frac{k(V_a)(\Delta T_4)}{E_t/100}\right)}{k(V_a)(\Delta T_3)(t)} \times 100\%$$

Where,

ΔT_3 = Average value of the outlet water temperature minus the average value of the ambient room temperature, expressed in °F

ΔT_4 = Final outlet water temperature measured at the end of the test minus the initial outlet water temperature measured at the start of the test, expressed in °F

k = 8.25 Btu/gallon·°F, the nominal specific heat of water

V_a = Volume of water contained in the water heater in gallons measured in accordance with section 4 of this appendix

E_t = Thermal efficiency—assume 98 percent for electric water heaters with immersed heating elements

E_c = Electrical energy consumed by the water heater during the duration of the test in Btu

t = Total duration of the test in hours

S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the heat content of the stored water above room temperature

16. Add appendix E to subpart G of part 431 to read as follows:

Appendix E to Subpart G of Part 431—Uniform Test Method for the Measurement of Thermal Efficiency and Standby Loss of Flow-Activated Instantaneous Water Heaters

Note: Prior to (*date 360 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to the energy use or efficiency of the subject commercial water heating equipment in accordance with the results of testing pursuant to this appendix or the procedures in 10 CFR 431.106 that were in place on January 1, 2016. On and after (*date 30 days after date of publication of the test procedure final rule in the* **Federal Register**), manufacturers must make any representations with respect to energy use or efficiency of flow-activated instantaneous water heaters in accordance with the results of testing pursuant to this appendix to demonstrate compliance with the energy conservation standards at 10 CFR 431.110.

1. General

Determine the thermal efficiency and standby loss (as applicable) in accordance with the following sections of this appendix. Certain sections reference sections of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105). Where the instructions contained in the sections below conflict with instructions in Annex E.1 of ANSI Z21.10.3–2015, the instructions contained herein control.

2. Test Set-Up

2.1. *Placement of Water Heater.* Place a water heater for installation on combustible floors on a ¾-inch plywood platform supported by three 2 x 4-inch runners. If the water heater is for installation on noncombustible floors, place suitable noncombustible material on the platform. When the use of the platform for a large water heater is not practical, the water heater may be placed on any suitable flooring. Mount a wall-mounted water heater to a simulated wall section.

2.2. *Test Configuration.* Set up the instantaneous water heater in accordance with Figure 4 in section 2.2 of appendix C to this subpart.

2.2.1. If the instantaneous water heater does not have any external piping, install a supply water valve within 5 inches of the water heater jacket, and install an outlet water valve within 10 inches of the water heater jacket. If the instantaneous water heater or hot water supply boiler includes external piping assembled at the manufacturer's premises prior to shipment, install water valves in the supply and outlet piping (as applicable) within 5 inches of the end of the piping supplied with the unit.

2.2.2. If the water heater is not able to achieve an outlet water temperature of 70 °F ± 2 °F above the supply water temperature at a constant maximum fuel input rate, a recirculating loop with pump as shown in Figure 4 in appendix C to this subpart must be used for conducting the tests.

2.2.2.1. If a recirculating loop with a pump is used then ensure that the inlet water temperature labeled as T_5 in Figure 4 in section 2.2 of appendix C to this subpart, is greater than or equal to 70 °F and less than or equal to 120 °F at all times during the thermal efficiency test and while achieving steady-state conditions prior to the standby loss test.

2.3. *Installation of Temperature-Sensing Means.* The temperature-sensing means must be installed in a manner such that the tip or the junction of the temperature sensing probe is in the water; less than or equal to 5 inches away from the outer casing of the equipment being tested; in the line of the central axis of the water pipe; and enclosed in a radiation protection shield. Figure 4 in section 2.2 of appendix C to this subpart shows the placement of the outlet water temperature-sensing instrument at a maximum distance of 5 inches away from the surface of the jacket of the equipment being tested. For water heaters with multiple outlet water connections leaving the water heater jacket, temperature-sensing means must be installed for each outlet water connection leaving the water heater in accordance with the provisions in this section.

2.4. *Piping Insulation.* Insulate all water piping external to the water heater jacket, including piping that are installed by the manufacturer or shipped with the unit, for at least 4 ft of piping length from the connection at the appliance with material having an R-value not less than 4 °F·ft^2·h/Btu. Ensure that the insulation does not contact any appliance surface except at the location where the pipe connections penetrate the appliance jacket.

2.5. *Temperature and Pressure Relief Valve Insulation.* If the manufacturer has not provided a temperature and pressure relief valve, one shall be installed and insulated as specified in section 2.4 of this appendix.

2.6. *Vent Requirements.* Follow the requirements for venting arrangements specified in section c of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105).

2.7. *Energy Consumption.* Install equipment that determines, within ± 1 percent:

2.7.1. The quantity and rate of fuel consumed (for gas-fired and oil-fired equipment).

2.7.2. The quantity of electricity consumed by factory-supplied water heater components, and of the test loop recirculating pump, if used.

3. Test Conditions

3.1. *Water Supply.* Follow the following provisions regarding the water supply to the water heater:

3.1.1. The pressure of the water supply must be maintained between 40 psi and the maximum pressure specified by the manufacturer of the unit being tested. If the maximum water pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default maximum value of 150 psi is to be used. The accuracy of the pressure-measuring devices must be ± 1.0 pounds per square inch (psi).

3.1.2. During conduct of the thermal efficiency test, the temperature of the supply water must be maintained at 70 °F ± 2 °F.

3.2. *Gas Supply Pressure for Gas-Fired Equipment.* The outlet pressure of the gas appliance pressure regulator must be within the range specified by the manufacturer. If the allowable range of gas supply pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then the outlet pressure of the gas appliance regulator must be within the default range of 4.5 inches water column (in. w.c.) to 10.5 in w.c. for natural gas-powered units or 11 in. w.c. to 13 in. w.c. for propane-powered units. Obtain the higher heating value of the gas burned.

3.3. *Ambient Room Temperature.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency test and standby loss tests (as applicable), maintain the ambient room temperature at 75 °F ± 5 °F at all times. Measure the ambient room temperature at 30-second intervals during these periods. Measure the ambient room temperature at the vertical mid-point of the water heater and approximately 2 feet from the water heater jacket. Shield the sensor against radiation. Calculate the average ambient room temperature separately for the thermal efficiency and standby loss tests (as applicable). The ambient room temperature must not vary more than ±2.0 °F at any reading from the average ambient room temperature.

3.4. *Test Air Temperature.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency test, the test air temperature must not vary by more than ±5 °F from the ambient room temperature at any reading. Measure the test air temperature at 30-second intervals during these periods and at a location within two feet of the air inlet of the water heater. For units with multiple air inlets, measure the test air temperature at each air inlet, and maintain the specified tolerance on deviation from the ambient room temperature at each air inlet. For CWH equipment without a specific air inlet, measure the test air temperature within two feet of a location on the water heater where combustion air is drawn.

3.5. *Ambient Humidity.* While verifying steady-state operation (prior to the thermal efficiency test) and during the thermal efficiency test, maintain the ambient relative humidity of the test room at 60 percent ±5 percent during these periods. Measure the ambient relative humidity at 30-second intervals during conduct of the test(s). The ambient relative humidity must be measured at the same location as the test air temperature. For units that have multiple air inlets, measure the ambient relative humidity at each air inlet, and maintain 60 percent ± 5 percent relative humidity at each air inlet.

3.6. *Maximum Air Draft.* During the thermal efficiency and standby loss tests (as applicable), the water heater must be located in an area protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement. Prior to beginning the thermal efficiency and standby loss tests (as applicable), measure the air draft within three feet of the jacket of the water heater to ensure this condition is met. Ensure that no other changes that would increase the air draft are made to the test set up or conditions during the conduct of the tests.

3.7. *Additional Conditions for Units With Multiple Outlet Water Connections.* For units with multiple outlet water connections leaving the water heater, use the following provisions:

3.7.1. The outlet water temperature measured from each connection leaving the water heater must be maintained at 70 °F ± 2 °F above the supply water temperature and must not differ from any other outlet water connection by more than 2 °F during the thermal efficiency test.

3.7.2. To calculate the outlet water temperature representative for the entire unit, calculate the average of the outlet water temperature measured at each connection leaving the water heater jacket. This average must be taken for each reading recorded by the data acquisition unit. The outlet water temperature obtained for each reading must be used for carrying out all calculations for the thermal efficiency and standby loss tests.

3.8. *Additional Requirements for Oil-Fired Equipment.*

3.8.1. *Venting Requirements.* Connect a vertical length of flue pipe to the flue gas outlet of sufficient height so as to meet the minimum draft specified by the manufacturer.

3.8.2. *Oil Supply.* Adjust the burner rate so that the following conditions are met:

3.8.2.1. The CO_2 reading is within the range specified by the manufacturer;

3.8.2.2. The fuel pump pressure is within ±10 percent of manufacturer's specifications;

3.8.2.3. If either the fuel pump pressure or range for CO_2 reading are not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default value of 100 psig is to be used for fuel pump pressure, and a default range of 9–12 percent is to be used for CO_2 reading; and

3.8.2.4. Smoke in the flue does not exceed No. 1 smoke as measured by the procedure in ASTM D2156–09 (incorporated by reference, see § 431.105). To determine the smoke spot number, the smoke measuring device shall be connected to an open-ended tube. This tube must project into the flue ¼ to ½ of the pipe diameter.

3.8.2.5. For the thermal efficiency test, measure the CO_2 reading and determine the smoke spot number after steady-state operation has been obtained as determined by no variation of outlet water temperature in excess of 2 °F over a 3-minute period, but before beginning measurements for the thermal efficiency test. However, measurement of the CO_2 reading and conduct of the smoke spot test are not required prior to beginning the thermal efficiency test if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously run thermal efficiency test.

3.9. *Data Collection Intervals.* Follow the data recording intervals specified in the following sections.

3.9.1. *Thermal Efficiency Test.* Follow the data recording intervals specified in Table 3.1 for gas-fired and oil-fired CWH equipment.

TABLE 3.1—DATA TO BE RECORDED BEFORE AND DURING THE THERMAL EFFICIENCY TEST

Item recorded	Before test	Every 30 seconds[1]	Every 10 minutes
Gas outlet pressure, in w.c.	X		
Fuel higher heating value, Btu/ft³ (gas) or Btu/lb (oil)	X		
Oil pump pressure, psig (oil only)	X		
CO_2 reading, % (oil only)	X[2]		
Oil smoke spot reading (oil only)	X[2]		
Air draft, ft/min	X		
Time, minutes/seconds		X	
Fuel weight or volume, lb (oil) or ft³ (gas)			X[3]
Supply water temperature, °F		X	
Outlet water temperature, °F		X	
Ambient room temperature, °F		X	
Test air temperature, °F		X	
Ambient relative humidity, %		X	

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

[2] The smoke spot test and CO_2 reading are not required prior to beginning the thermal efficiency test if no settings on the water heater have been changed and the water heater has not been turned off since the end of a previously-run thermal efficiency test.

[3] Fuel and electricity consumption over the course of the entire test must be measured and used in calculation of thermal efficiency.

3.9.2. *Standby Loss Test.* Follow the data recording intervals specified in Table 3.2 of this section. Additionally, the fuel and electricity consumption must be measured over the course of the entire test and used in calculation of standby loss.

TABLE 3.2—DATA TO BE RECORDED BEFORE AND DURING THE STANDBY LOSS TEST

Item recorded	Before test	Every 30 seconds[1]
Air draft, ft/min	X	
Time, minutes/seconds		X
Outlet water temperature, °F		X
Ambient room temperature, °F		X

Note:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

4. *Determination of Storage Volume.* Determine the storage volume by subtracting the tare weight—measured while the system is dry and empty—from the weight of the system when filled with water and dividing the resulting net weight of water by the density of water at the measured water temperature.

5. *Thermal Efficiency Test.* For gas-fired and oil-fired CWH equipment, conduct the thermal efficiency test as specified in section j of Annex E.1 of ANSI Z21.10.3–2015 (incorporated by reference; see § 431.105), with the exception of the provision stipulating the data collection intervals for water temperatures. Additionally, follow the provisions in the following sections:

5.1. *Steady-State Conditions.* Adjust the water flow rate to a constant value such that the following conditions are always satisfied during the test. Once steady-state operation is achieved, as determined by no variation of the outlet water temperature in excess of 2 °F over a 3-minute period, do not change any settings on the water heating equipment until measurements for the thermal efficiency test are finished.

5.1.1. The outlet water temperature must be maintained at 70 °F ± 2 °F above the supply water temperature.

5.1.2. The burner must fire continuously at full firing rate (*i.e.,* no modulation or cut-outs) for the entire duration of the thermal efficiency test.

5.2. *Determination of Fuel Input Rate.* For the thermal efficiency test, record the fuel consumption at 10-minute intervals. Calculate the fuel input rate for each 10-minute period using the equations in section 5.3 of this appendix. The measured fuel input rates for these 10-minute periods must not vary by more than ±2 percent between any two readings. Determine the overall fuel input rate using the fuel consumption for the entire duration of the thermal efficiency test. Round the overall fuel input rate to the nearest 1,000 Btu/h.

5.3. *Fuel Input Rate Calculation.* To calculate the fuel input rate, use the following equations:

5.3.1. For gas-fired CWH equipment, calculate the fuel input rate using the following equation:

$$Q = \frac{Q_s * C_s * H_{gas}}{t}$$

Where,

Q = Fuel input rate, expressed in Btu/h
Q_s = Total fuel flow as metered, ft^3
C_s = Correction applied to the heating value of a gas H_{gas}, when it is metered at temperature and/or pressure conditions other than the standard conditions for which the value of H_{gas} is based
H_{gas} = Higher heating value of a gas, Btu/ft^3
t = Duration of measurement of fuel consumption

5.3.2. For oil-fired CWH equipment, calculate the fuel input rate using the following equation:

$$Q = \frac{Q_s * H_{oil}}{t}$$

Where,

Q = Fuel input rate, expressed in Btu/h
Q_s = Total weight of fuel, lb
H_{oil} = Higher heating value of a gas, Btu/lb
t = Duration of measurement of fuel consumption

6. Standby Loss Test

6.1. Initiate normal operation of the water heater. Prior to beginning the standby loss test, unless no settings on the water heater were changed and the water heater has not been turned off since the completion of the thermal efficiency test, achieve steady-state conditions for the outlet water temperature using the following provisions: set the supply water temperature to 70 °F ± 2 °F. Adjust the water flow rate to attain an outlet water temperature of 70 °F ± 2 °F above the supply water temperature. Once the outlet water temperature is achieved, maintain the flow rate such to ensure that the outlet water temperature does not vary in excess of 2 °F over a 3-minute period.

6.2. After ensuring the outlet water temperature is constant or if no settings on the water heater have been changed and the water heater has not been turned off since completion of the thermal efficiency test, turn off the supply water valve(s) and the outlet water valve(s) (installed as per the provisions in section 2.2 of this appendix), and the water pump simultaneously and ensure that there is no flow of water through the water heater. Allow the water heater to cut out. After the burner or heating element cuts out, start recording the measurements for the standby loss test.

6.3. At this time, record the time as $t = 0$ and record the initial outlet water temperature, ambient room temperature, and fuel and electricity meter readings. Continue to monitor and record the outlet water temperature, the time elapsed from the start of the test, and the electricity consumption at 30-second intervals using a data acquisition system.

6.4. Stop the test when one of the following occurs:

(1) The outlet water temperature decreases by 35 °F from the initial outlet temperature within 24 hours from the start of the test, or

(2) 24 hours has elapsed from the start of the test.

Record the final outlet water temperature, fuel consumed, electricity consumed, and the time elapsed from the start of the test.

6.5. Once the test is complete, use the applicable equation to calculate the standby loss in percent per hour:

For gas-fired equipment:

t = Total duration of the test in hours
C_s = Correction applied to the heating value of a gas H, when it is metered at temperature and/or pressure conditions other than the standard conditions upon which the value of H is based.
Q_s = Total fuel flow as metered, expressed in ft^3 (gas) or lb (oil)
H = Higher heating value of gas or oil, expressed in Btu/ft^3 (gas) or Btu/lb (oil)
S = Standby loss, the average hourly energy required to maintain the stored water temperature expressed as a percentage of the initial heat content of the stored water above room temperature

6.6. For gas-fired and oil-fired flow-activated instantaneous water heaters, calculate the standby loss in terms of Btu per hour as follows:

SL (Btu per hour) = S (% per hour) × 8.25 (Btu/gal-°F) × Measured Volume (gal) × 70 (°F)

Where, SL refers to the standby loss of the water heater, defined as the amount of energy required to maintain the stored water temperature expressed in Btu per hour.

■ 17. Add appendix F to subpart G of part 431 to read as follows:

Appendix F to Subpart G of Part 431—Uniform Test Method for the Measurement of Energy Efficiency of Commercial Heat Pump Water Heaters

Note: On and after (*date 360 days after date of publication of the test procedure final rule in the **Federal Register***), manufacturers must make any representations with respect to energy use or efficiency of commercial heat pump water heaters in accordance with the results of testing pursuant to this appendix.

1. *General.* Determine the COP$_h$ for CHPWHs using the test procedure set forth below. Certain sections below reference ASHRAE 118.1–2012 (incorporated by reference; see § 431.105). Where the instructions contained below differ from those contained in ASHRAE 118.1–2012, the *sections below control.*

2. *Definitions and Symbols.* The definitions and symbols are as listed in section 3 of ASHRAE 118.1–2012.

3. *Instrumentation.* The instruments required for the test are as described in section 6 of ASHRAE 118.1–2012.

4. *Test Set-Up.* Follow the provisions described in this section to install the CHPWH for testing.

4.1. Test set-up and installation instructions

4.1.1. For air-source CHPWHs, set up the unit for testing as per section 7.1 and Figure 5a in section 7.7.1 of ASHRAE 118.1–2012.

4.1.2. For direct geo-exchange CHPWHs, set up the unit for testing as per section 7.1 and Figure 5b in section 7.7.2 of ASHRAE 118.1–2012.

4.1.3. For indoor water-source and ground water-source CHPWHs, set up the unit for testing as per section 7.1 and Figure 5c in section 7.7.3 of ASHRAE 118.1–2012.

4.2. Use the water piping instructions described in section 7.2 of ASHRAE 118.1–2012 and the special instructions described in section 7.7.6 of ASHRAE 118.1–2012. Insulate all the pipes used for connections with material having a thermal resistance of not less than 4 h·°F·ft^2/Btu for a total piping length of not less than 4 feet from the water heater connection ports.

4.3. Install the thermocouples, including the room thermocouples, as per the instructions in sections 7.3.2 and 7.3.3 of ASHRAE 118.1–2012.

4.4. Section 7.6 of ASHRAE 118.1–2012 must be used if the manufacturer neither submits nor specifies a water pump applicable for the unit for laboratory testing.

4.5. Install the temperature sensors at the locations specified in Figure 5a, 5b, or 5c as applicable as per section 4.1 of this appendix. The sensor shall be installed in such a manner that the sensing portion of the device is positioned within the water flow and as close as possible to the center line of the pipe. Follow the instructions provided in sections 7.7.7.1 and 7.7.7.2 of ASHRAE 118.1–2012 to install the temperature and flow-sensing instruments.

4.6. Use the following evaporator side rating conditions as applicable for each category of CHPWHs. These conditions are also mentioned in Table 4 of this appendix:

4.6.1. For air-source CHPWHs, maintain the evaporator air entering dry-bulb temperature at 80.6 °F ± 1 °F and wet-bulb temperature at 71.2 °F ± 1 °F throughout the conduct of the test.

4.6.2. For direct geo-exchange CHPWHs, maintain the evaporator refrigerant temperature at 32 °F ± 1 °F.

4.6.3. For indoor water-source CHPWHs, maintain the evaporator entering water temperature at 68 °F ± 1 °F.

4.6.4. For ground water-source CHPWHs, maintain the evaporator entering water temperature at 50 °F ± 1 °F.

4.7. The CHPWH being tested must be installed as per the instructions specified in sections 4.1 to 4.6 (as applicable) of this appendix. For all other installation requirements, use section 7.7.4 of ASHRAE 118.1–2012 to resolve any issues related to installation (other than what is specified in this test procedure) of the equipment for testing. Do not make any alterations to the equipment except as specified in this appendix for installation, testing, and the attachment of required test apparatus and instruments.

4.8. Use Table 3 of ASHRAE 118.1–2012 for measurement tolerances of various parameters.

4.9. If the CHPWH is equipped with a thermostat that is used to control the throttling valve of the equipment then use the provisions in section 7.7.7.3 of ASHRAE 118.1–2012 to set up the thermostat.

5. Test Procedure

Test all CHPWHs as per the provisions described in ASHRAE 118.1–2012 for "Type IV" equipment. Tests for all CHPWH equipment must follow the steps described below.

5.1. Supply the CHPWH unit with electricity at the voltage specified by the manufacturer. Follow the provisions in section 8.2.1 of ASHRAE 118.1–2012 to maintain the electricity supply at the required level.

5.2. Set the condenser supply water temperature and outlet water temperature per the following provisions and as set forth in Table 5.1 of this section:

TABLE 5.1—EVAPORATOR AND CONDENSER SIDE RATING CONDITIONS

Category of CHPWH	Evaporator side rating conditions	Condenser side rating conditions
Air-source commercial heat pump water heater	Evaporator entering air conditions: Dry bulb: 80.6 °F ± 1 °F Wet bulb: 71.2 °F ± 1 °F	Entering water temperature: 70 °F ± 1 °F. Vary water flow rate (if needed) to achieve the outlet water temperature as specified in section 8.7.2 of ASHRAE 118.1–2012. If the required outlet water temperature as specified in section 8.7.2 of ASHRAE 118.1–2012 is not met even after varying the flow rate, then change the condenser entering water temperature to 110 °F ± 1 °F. Vary flow rate to achieve the conditions in section 8.7.2 of ASHRAE 118.1–2012.
Direct geo-exchange commercial heat pump water heater.	Evaporator refrigerant temperature: 32 °F ± 1 °F.	Entering water temperature: 110 °F ± 1 °F.
Indoor water-source commercial heat pump water heater.	Evaporator entering water temperature: 68 °F ± 1 °F.	Entering water temperature: 110 °F ± 1 °F.
Ground water-source commercial heat pump water heater.	Evaporator entering water temperature: 50 °F ± 1 °F.	Entering water temperature: 110 °F ± 1 °F.

5.2.1. For air-source CHPWHs:

5.2.1.1. Set the supply water temperature to 70 °F ± 1 °F.

5.2.1.2. Initiate operation at the rated pump flow rate and measure the outlet water temperature. If the outlet water temperature is maintained at 120 °F ± 5 °F with no variation in excess of 2 °F over a three-minute period, as required by section 8.7.2 of ASHRAE 118.1–2012, skip to section 5.3 of this appendix.

5.2.1.3. If the outlet water temperature condition as specified in section 8.7.2 of ASHRAE 118.1–2012 is not achieved, adjust the water flow rate over the range of the pump's capacity. If, after varying the water flow rate, the outlet water temperature is maintained at 120 °F ± 5 °F with no variation in excess of 2 °F over a three-minute period, as required by section 8.7.2 of ASHRAE 118.1–2012, skip to section 5.3 of this appendix.

5.2.1.4. If, after adjusting the water flow rate within the range that is achievable by the pump, the outlet water temperature condition as specified in section 8.7.2 of ASHRAE 118.1–2012 is still not achieved, then change the supply water temperature to 110 °F ± 1 °F and repeat the instructions from sections 5.2.1.2 and 5.2.1.3 of this appendix.

5.2.1.5. If the outlet water temperature condition cannot be met, then a test procedure waiver is necessary to specify an alternative set of test conditions.

5.2.2. For direct geo-exchange, indoor water-source, and ground water-source CHPWHs use the following steps:

5.2.2.1. Set the condenser supply water temperature to 110 °F ± 1 °F.

5.2.2.2. Follow the steps specified in section 8.7.2 of ASHRAE 118.1–2012 to obtain an outlet water temperature of 120 °F ± 5 °F with no variation in excess of 2 °F over a three-minute period.

5.3. Conduct the test as per section 9.1.1, "Full Input Rating," of ASHRAE 118.1–2012. The flow rate, "FR," referred to in section 9.1.1 of ASHRAE 118.1–2012 is the flow rate of water through the CHPWH expressed in gallons per minute obtained after following the steps in section 5.2 of this appendix. Use the evaporator side rating conditions specified in section 4.6 of this appendix to conduct the test as per section 9.1.1 of ASHRAE 118.1–2012.

5.4. Calculate the COP_h of the CHPWH according to section 10.3.1 of the ASHRAE 118.1–2012 for the "Full Capacity Test Method."

■ 18. Add appendix G to subpart G of part 431 to read as follows:

Appendix G to Subpart G of Part 431—Uniform Test Method for the Measurement of Energy Efficiency of Unfired Hot Water Storage Tanks

Note: On and after (*date 360 days after date of publication of the test procedure final rule in the **Federal Register***), manufacturers must make any representations with respect to energy use or efficiency of unfired hot water storage tanks in accordance with the results of testing pursuant to this appendix.

1. General

Determine the standby loss in accordance with the following sections of this appendix. Certain sections reference sections of GAMA Testing Standard IWH–TS–1 (incorporated by reference; see § 431.105). Where the instructions contained in the sections below conflict with instructions in GAMA IWH–TS–1, the instructions contained herein control.

2. *Test Set-Up.* Set up the unfired hot water storage tank for testing in accordance with sections 4, 5 (except for section 5.5), 6.0, and 6.1 of GAMA IWH–TS–1.

2.1. *Piping Insulation.* Insulate all water piping external to the water heater jacket, including heat traps and piping that are installed by the manufacturer or shipped with the unit, for at least 4 ft of piping length from the connection at the appliance with material having an R-value not less than 4 °F·ft²·h/Btu. Ensure that the insulation does not contact any appliance surface except at the location where the pipe connections penetrate the appliance jacket.

3. Test Conditions

3.1. *Water Supply.* Follow the following provisions regarding the water supply to the water heater:

3.1.1. The pressure of the water supply must be maintained between 40 psi and the maximum pressure specified by the manufacturer of the unit being tested. If the maximum water pressure is not specified by the manufacturer in literature shipped with the unit or supplemental test report instructions included with a certification report, then a default maximum value of 150 psi is to be used. The accuracy of the pressure-measuring devices must be ± 1.0 pounds per square inch (psi).

3.2. *Ambient Room Temperature.* During the soak-in period and standby loss test, maintain the ambient room temperature at 75 °F ± 5 °F at all times. Measure the ambient room temperature at 30-second intervals during these periods. Measure the average ambient room temperature separately for the soak-in period and standby loss test. During the soak-in period and standby loss test, the measured room temperature must not vary more than ±2.0 °F at any reading from the average ambient room temperature.

3.3. *Maximum Air Draft.* During the soak-in period and standby loss test, the storage tank must be located in an area protected from drafts of more than 50 ft/min from room ventilation registers, windows, or other external sources of air movement. Prior to beginning the soak-in period and standby loss test, measure the air draft within three feet of the jacket of the water heater to ensure this condition is met. Ensure that no other changes that would increase the air draft are made to the test set up or conditions during conduct of the test.

3.4. *Data Collection Intervals.* Follow the data recording intervals specified in the following sections.

3.4.1. *Soak-In period.* Measure the air draft, in ft/min, before beginning the soak-in period. Measure the ambient room temperature, in °F, every 30 seconds during the soak-in period.

3.4.2. *Standby Loss Test.* Follow the data recording intervals specified in Table 3.1 of this section.

TABLE 3.1—DATA TO BE RECORDED BEFORE AND DURING THE STANDBY LOSS TEST

Item recorded	Before test	Every 30 seconds [1]
Air draft, ft/min	X	
Time, minutes/seconds		X
Mean tank temperature, °F		X
Ambient room temperature, °F		X

Notes:

[1] These measurements are to be recorded at the start and end of the test, as well as every 30 seconds during the test.

4. *Determination of Storage Volume.* Determine the storage volume by subtracting the tare weight—measured while the system is dry and empty—from the weight of the system when filled with water and dividing the resulting net weight of water by the density of water at the measured water temperature.

5. *Soak-In Period.* Prior to conducting a standby loss test, a soak-in period must occur, in which the tank must sit without any draws taking place for at least 12 hours. Begin the soak-in period after filling the tank with water such that a mean tank temperature of 145 °F ± 5 °F is achieved.

6. Standby Loss Test

6.1. After conduct of the soak-in period but prior to the start of the standby loss test, fill the storage tank with water that is heated sufficiently to achieve a mean tank temperature of at least 145 °F.

6.2. When the mean tank temperature falls to 142 °F, start recording mean tank temperature and ambient room temperature at regular 30-second intervals as the tank temperature decays.

6.3. When the mean tank temperature falls below 138 °F, stop the test and record the final mean tank temperature reading.

6.4. Calculate the standby loss in Btu per hour as follows:

6.4.1. Select the data points starting when the mean tank temperature first falls to 142 °F and ending when the mean tank temperature first falls below 138 °F. Calculate the uncorrected decay rate, DR_u in °F/h, by a least squares method as given by:

$$DR_u = \frac{n \sum x_i T_i - (\sum x_i)(\sum T_i)}{n \sum (x_i^2) - (\sum x_i)^2}$$

Where:

n = Number of data points collected;

x_i = Elapsed time of each data point from the start of the decay period when the tank first achieves a mean temperature of 142 °F (hours);

T_i = Mean tank temperature in °F measured at each 30-second interval during the decay period between the time when the mean tank temperature first falls to 142 °F and when the mean tank temperature drops below 138 °F.

6.4.2. Calculate the mean tank water temperature decay rate, DR, in °F/h, as follows:

$$DR = DR_u \times \frac{140\text{ °F} - 75\text{ °F}}{140\text{ °F} - T_a}$$

Where T_a is the average ambient room temperature during the test, °F.

6.4.3. The standby loss, SL, in Btu per hour, for unfired hot water storage tanks is determined as:

$SL = DR \times V \times \rho \times C_p$

Where:

V = tank volume expressed in gallons, measured in accordance with section 2.4 of this appendix

ρ = 8.205 pounds per gallon, density of water at 140 °F

C_p = 0.999 Btu per pound-mass·°F, specific heat of water at 140 °F.

[FR Doc. 2016–09539 Filed 5–6–16; 8:45 am]

BILLING CODE 6450–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

1985

FEDERAL REGISTER

Vol. 81 Monday,
No. 89 May 9, 2016

Part IV

Department of Justice

28 CFR Part 35

Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities; Proposed Rules

DEPARTMENT OF JUSTICE

28 CFR Part 35

[CRT Docket No. 128]

RIN 1190–AA65

Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities

AGENCY: Civil Rights Division, Department of Justice.

ACTION: Supplemental advance notice of proposed rulemaking.

SUMMARY: The Department of Justice (Department) is considering revising the regulation implementing title II of the Americans with Disabilities Act (ADA or Act) in order to establish specific technical requirements to make accessible the services, programs, or activities State and local governments offer to the public via the Web. In 2010, the Department issued an Advance Notice of Proposed Rulemaking (2010 ANPRM) titled *Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations.* The purpose of this Supplemental Advance Notice of Proposed Rulemaking (SANPRM) is to solicit additional public comment specifically regarding the regulation implementing title II, which applies to State and local government entities. Specifically, the Department is issuing this SANPRM in order to solicit public comment on various issues relating to the potential application of such technical requirements to the Web sites of title II entities and to obtain information for preparing a regulatory impact analysis.

DATES: The Department invites written comments from members of the public. Written comments must be postmarked and electronic comments must be submitted on or before August 8, 2016.

ADDRESSES: You may submit comments, identified by RIN 1190–AA65 (or Docket ID No. 128), by any one of the following methods:

- *Federal eRulemaking Web site: www.regulations.gov.* Follow the Web site's instructions for submitting comments.
- *Regular U.S. mail:* Disability Rights Section, Civil Rights Division, U.S. Department of Justice, P.O. Box 2885, Fairfax, VA 22031–0885.
- *Overnight, courier, or hand delivery:* Disability Rights Section, Civil Rights Division, U.S. Department of Justice, 1425 New York Avenue NW., Suite 4039, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Rebecca Bond, Chief, Disability Rights Section, Civil Rights Division, U.S. Department of Justice, at (202) 307–0663 (voice or TTY). This is not a toll-free number. Information may also be obtained from the Department's toll-free ADA Information Line at (800) 514–0301 (voice) or (800) 514–0383 (TTY). You may obtain copies of this Supplemental Advance Notice of Proposed Rulemaking (SANPRM) in an alternative format by calling the ADA Information Line at (800) 514–0301 (voice) or (800) 514–0383 (TTY). This SANPRM is also available on the ADA Web site at *www.ada.gov.*

Electronic Submission of Comments and Posting of Public Comments: You may submit electronic comments to *www.regulations.gov.* When submitting comments electronically, you must include CRT Docket No. 128 in the subject box, and you must include your full name and address. Electronic files should avoid the use of special characters or any form of encryption and should be free of any defects or viruses.

Please note that all comments received are considered part of the public record and will be made available for public inspection online at *www.regulations.gov.* Posting of submission will include any personal identifying information (such as your name and address) included in the text of your comment. If you include personal identifying information in the text of your comment but do not want it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also include all the personal identifying information you want redacted along with this phrase. Similarly, if you submit confidential business information as part of your comment but do not want it posted online, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory History

On July 26, 1990, President George H.W. Bush signed into law the ADA, a comprehensive civil rights law prohibiting discrimination on the basis of disability. The ADA broadly protects the rights of individuals with disabilities as to employment, access to State and local government services, places of public accommodation, transportation, and other important areas of American life. The ADA also requires newly designed and constructed or altered State and local government facilities, public accommodations, and commercial facilities to be readily accessible to and usable by individuals with disabilities. 42 U.S.C. 12101 *et seq.* Section 204(a) of title II and section 306(b) of title III direct the Attorney General to promulgate regulations to carry out those titles, other than certain provisions dealing specifically with transportation. 42 U.S.C. 12134; 42 U.S.C. 12186(b).

Title II applies to State and local government entities, and, in subtitle A, protects qualified individuals with disabilities from discrimination on the basis of disability in services, programs, and activities provided by State and local government entities. Title II extends the prohibition on discrimination established by section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (section 504), to all activities of State and local governments regardless of whether these entities receive Federal financial assistance. 42 U.S.C. 12131–65.

Title III prohibits discrimination on the basis of disability in the full and equal enjoyment of places of public accommodation (privately operated entities whose operations affect commerce and that fall into one of 12 categories listed in the ADA, such as restaurants, movie theaters, schools, day care facilities, recreational facilities, and doctors' offices) and requires newly constructed or altered places of public accommodation—as well as commercial facilities (privately owned, nonresidential facilities, such as factories, warehouses, or office buildings)—to comply with the ADA Standards for Accessible Design (ADA Standards). 42 U.S.C. 12181–89.

B. Rulemaking History

On July 26, 1991, the Department issued its final rules implementing title II and title III, codified at 28 CFR part 35 (title II) and part 36 (title III), which included the ADA Standards. At that time, the Web was in its infancy and was not used by State and local governments as a means of providing services or information to the public and thus was not mentioned in the Department's title II regulation.

In June 2003, in recognition of how the Internet was transforming interactions between the public and governmental entities, the Department published a document entitled *Accessibility of State and Local Government Web sites to People with Disabilities*, available at *http://www.usdoj.gov/crt/ada/Web sites2.htm*, which provides State and local governments guidance on how to make their Web sites accessible to ensure that persons with disabilities have equal access to the services, programs, and activities that are provided through those Web sites. This guidance recognizes that, increasingly, State and local governments are using their Web sites to allow services, programs, and activities to be offered in a more dynamic and interconnected way, which serves to do all of the following: increase citizen participation; increase convenience and speed in obtaining information or services; reduce costs in providing programs and information about government services; reduce the amount of paperwork; and expand the possibilities of reaching new sectors of the community or offering new programs. The guidance also provides that State and local governments might be able to meet their title II obligations by providing an alternative accessible means of obtaining the Web site's information and services (*e.g.*, a staffed telephone line). However, that guidance makes clear that alternative means would be "unlikely to provide an equal degree of access in terms of hours of operation and the range of options and programs available." *Accessibility of State and Local Government Web sites to People with Disabilities*, available at *http://www.usdoj.gov/crt/ada/web sites2.htm*. This is even more true today, almost 13 years later, when the amount of information and complexity of Web sites has increased exponentially.

On September 30, 2004, the Department published an Advance Notice of Proposed Rulemaking (2004 ANPRM) to begin the process of updating the 1991 regulations to adopt revised ADA Standards based on the relevant parts of the ADA and Architectural Barriers Act Accessibility Guidelines (2004 ADA/ABA Guidelines). 69 FR 58768 (Sept. 30, 2004). On June 17, 2008, the Department issued a Notice of Proposed Rulemaking (2008 NPRM) to adopt the revised 2004 ADA/ABA Guidelines and revise the title II and title III regulations. 73 FR 34466 (June 17, 2008). The 2008 NPRM addressed the issues raised in the public's comments to the 2004 ANPRM and sought additional comment.

The Department did not propose to include Web accessibility provisions in the 2004 ANPRM or the 2008 NPRM, but the Department received numerous comments urging the Department to issue Web accessibility regulations under the ADA. Although the final title II rule, published on September 15, 2010, did not include specific requirements for Web accessibility, the guidance accompanying the final title II rule responded to these comments. *See* 28 CFR part 35, app. A, 75 FR 56163, 56236 (Sept. 15, 2010). In that guidance, the Department stated that since the ADA's enactment in 1990, the Internet had emerged as a critical means to provide access to public entities' programs and activities. *Id. at 56236.* The Department reiterated its position that title II covers public entities' Web sites and noted that it has enforced the ADA in this area on a case-by-case basis and that it intended to engage in future rulemaking on this topic. *Id.* The Department stated that public entities must ensure equal access to Web-based programs and activities for individuals with disabilities unless doing so would result in an undue financial and administrative burden or fundamental alteration. *Id.*

On July 26, 2010, the Department published an ANPRM titled *Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations.* 75 FR 43460 (July 26, 2010). The 2010 ANPRM announced that the Department was considering revising the regulations implementing titles II and III of the ADA to establish specific requirements for State and local governments and public accommodations to make their Web sites accessible to individuals with disabilities. In the 2010 ANPRM, the Department sought information regarding what standards, if any, it should adopt for Web accessibility; whether the Department should adopt coverage limitations for certain entities, like small businesses; and what resources and services were available to make existing Web sites accessible to individuals with disabilities. The Department also requested comments on the costs of making Web sites accessible; whether there are effective and reasonable alternatives to making Web sites accessible that the Department should consider permitting; and when any Web accessibility requirements adopted by the Department should become effective. The Department received approximately 400 public comments addressing issues germane to both titles II and III in response to the 2010 ANPRM. Upon review of those comments, the Department announced in 2015 that it decided to pursue separate rulemakings addressing Web accessibility for titles II and III. *See Department of Justice—Fall 2015 Statement of Regulatory Priorities*, available at *http://www.reginfo.gov/public/jsp/eAgenda/StaticContent/201510/Statement_1100.html* (last visited Apr. 13, 2016). The Department is moving forward with rulemaking under title II first.

C. Need for Department Action

1. Use of Web sites by Title II Entities

As mentioned previously, title II entities are increasingly using the Internet to disseminate information and offer services, programs, and activities to the public. Today, among other things, public entities use Web sites to promote employment opportunities and economic growth, improve the collection of payments and fees, encourage civic participation, and enhance educational opportunities. However, individuals with disabilities are often denied equal access to many of these services, programs, and activities because many public entities' Web sites are inaccessible. Thus, there is a digital divide between the ability of citizens with disabilities and those without disabilities to access the services, programs, and activities of their State and local governments.

Public entities have created a variety of online Web portals to streamline their services, programs, and activities. Citizens can now make a number of online service requests—from requesting streetlight repairs and bulk trash pickups to reporting broken parking meters—and can often check the status of a service request online. Public entities also have improved the way citizens can obtain access to most common public services and pay fees and fines. Many States' Web sites now offer citizens the opportunity to renew their vehicle registrations, submit complaints, purchase event permits, and pay traffic fines and property taxes, making some of these otherwise time-consuming tasks easy to complete with a few clicks of a mouse at any time of the day or night. Moreover, many Federal benefits, such as unemployment benefits and food stamps, are available through State Web sites.

Public entities also use their Web sites to make civic participation easier. Many public entities allow voters to begin the voter registration process and obtain candidate information on their Web sites. Individuals interested in running for local public offices can often find pertinent information concerning candidate qualifications and filing requirements on these Web sites as well. Citizens can watch local public hearings, read minutes from community meetings, or take part in live chats with government officials on the Web sites of State and local government entities. The Web sites of public entities also include a variety of information about issues of concern to the community and how citizens can get involved in community efforts to improve the administration of government services.

Many public entities use online resources to promote employment opportunities and economic growth for their citizens. Individuals can use Web sites of public entities to file for unemployment benefits and find and apply for job openings. Pertinent job-related information and training opportunities are increasingly being provided on the Web sites of public entities. Through the Web sites of State and local governments, business owners can register their businesses, apply for occupational and professional licenses, bid on contracts to provide products and services to public entities, and obtain information about laws and regulations with which they must comply. The Web sites of many State and local governments also allow members of the public to research and verify business licenses online and report unsavory business practices.

Public entities are also using Web sites as a gateway to education. Public schools at all levels are offering programs and classroom instruction through Web sites. Some public colleges and universities now offer degree programs online. Many public colleges and universities rely on Web sites and other Internet-related technologies to allow prospective students to apply for admission, request on-campus living assignments, register for courses, access assignments and discussion groups, and to participate in a wide variety of administrative and logistical functions required for students and staff. Similarly, in elementary and secondary public school settings, communications via the Web are increasingly becoming the way teachers and administrators notify parents and students of grades, assignments, and administrative matters. These issues are also discussed in the 2010 ANPRM, *see* 75 FR 43460 (July 26, 2010).

2. Barriers to Web Accessibility

Millions of individuals in the United States have disabilities that affect their use of the Web. Many of these individuals use assistive technology to enable them to navigate Web sites or access information contained on those sites. For example, individuals who do not have use of their hands may use speech recognition software to navigate a Web site, while individuals who are blind may rely on a screen reader to convert the visual information on a Web site into speech. Many Web sites, however, fail to incorporate or activate features that enable users with disabilities to access all of the Web site's information or elements. For instance, individuals who are deaf are unable to access information in Web videos and other multimedia presentations that do not have captions. Individuals with low vision may be unable to read Web sites that do not allow text to be resized or do not provide sufficient contrast. Individuals with limited manual dexterity or vision disabilities who use assistive technology that enables them to interact with Web sites cannot access sites that do not support keyboard alternatives for mouse commands. These same individuals, along with individuals with intellectual and vision disabilities, often encounter difficulty using portions of Web sites that require timed responses from users but do not provide the option for users to indicate that they need more time to respond.

Individuals who are blind or have low vision often confront significant barriers to Web access. This is because many Web sites provide information visually without features that allow screen readers or other assistive technology to retrieve information on the Web site so it can be presented in an accessible manner. A common barrier to Web site accessibility is an image or photograph without corresponding text describing the image. A screen reader or similar assistive technology cannot "read" an image, leaving individuals who are blind with no way of independently knowing what information the image conveys. Similarly, complex Web sites often lack navigational headings or links that would facilitate navigation using a screen reader or may contain tables with header and row identifiers that display data but fail to provide associated cells for each header and row so that the table information can be interpreted by a screen reader.

Online forms, which are essential to accessing services on many government Web sites, are often inaccessible to individuals with disabilities who use screen readers. For example, field elements on forms, which are the empty boxes on forms that hold specific pieces of information, such as a last name or telephone number, may lack clear labels that can be read by assistive technology. Also, visual CAPTCHAs (Completely Automated Public Turing Test To Tell Computers and Humans Apart), which is distorted text that must be inputted by a Web site user to verify that a Web submission is being completed by a human rather than a computer, is not always accompanied by an audio CAPTCHA that is accessible. Inaccessible form fields and CAPTCHAs make it difficult for persons using screen readers to pay fees or fines, submit applications, and otherwise interact with a Web site. Some governmental entities use inaccessible third-party Web sites to accept online payments, while others request public input through inaccessible Web sites. These barriers greatly impede the ability of individuals with disabilities to access the services, programs, and activities offered by public entities on the Web. In many instances, removing certain Web site barriers is neither difficult nor especially costly. For example, the addition of invisible attributes known as alternative (alt) text or tags to an image, which can be done without any specialized equipment, will help keep an individual using a screen reader oriented and allow the individual to gain access to the information on the Web site. Similarly, headings, which also can be added easily, facilitate page navigation for those using screen readers. A discussion of barriers to Web access also appears in the 2010 ANPRM, *see* 75 FR 43460 (July 26, 2010).

3. Compliance With Voluntary Technical Accessibility Standards Has Been Insufficient in Providing Access

The Internet as it is known today did not exist when Congress enacted the ADA and, therefore, neither the ADA nor the regulations the Department promulgated under the ADA specifically address access to Web sites. Congress contemplated that the Department would apply the statute in a manner that evolved over time and delegated authority to the Attorney General to promulgate regulations to carry out the Act's broad mandate. *See* H.R. Rep. No. 101–485(II), 101st Cong., 2d Sess. 108 (1990); 42 U.S.C. 12186(b). Consistent with this approach, the Department stated in the preamble to the original 1991 ADA regulations that the regulations should be interpreted to keep pace with developing technologies. 28 CFR part 36, app. B. There is no doubt that the programs, services, and activities provided by State and local government entities on their Web sites are covered by title II of the ADA. *See* 28 CFR 35.102 (providing that the title II regulation "applies to all services, programs, and activities provided or made available by public entities").

Similarly, Web sites of recipients of Federal financial assistance are covered by section 504 of the Rehabilitation Act. As discussed above, the Department has affirmed the application of these statutes to Web sites in its technical assistance publication, *Accessibility of State and Local Government Web sites to People with Disabilities,* available at *http://www.usdoj.gov/crt/ada/Websites2.htm.* Despite the clear application of the ADA to public entities' Web sites, it seems that technical Web standards under the ADA will help provide public entities with more specific guidance on how to make the services, programs, and activities they offer on their Web sites accessible. The title II ADA regulation currently has such specific guidance with regard to physical structures through the ADA Standards, which provide technical requirements on how to make physical environments accessible. It seems that similar clarifying guidance for public entities in the Web context is also needed.

It has been the policy of the United States to encourage self-regulation with regard to the Internet wherever possible and to regulate only where self-regulation is insufficient and government involvement may be necessary. *See Memorandum on Electronic Commerce,* 33 WCPD 1006, 1006–1010 (July 1, 1997), available at *http://www.gpo.gov/fdsys/pkg/WCPD-1997-07-07/html/WCPD-1997-07-07-Pg1006-2.htm* (last visited Apr. 13, 2016); *The Framework for Global Electronic Commerce,* available at *http://clinton4.nara.gov/WH/New/Commerce* (last visited Apr. 13, 2016). A variety of voluntary standards and structures have been developed for the Internet through nonprofit organizations using multinational collaborative efforts. For example, the Internet Corporation for Assigned Names and Numbers (ICANN) issues and administers domain names, the Internet Society (ISOC) publishes computer security policies and procedures for Web sites, and the World Wide Web Consortium (W3C®) develops a variety of technical standards and guidelines ranging from issues related to mobile devices and privacy to internationalization of technology. In the area of accessibility, the Web Accessibility Initiative (WAI) of the W3C® created the Web Content Accessibility Guidelines (WCAG), which cover a wide range of recommendations for making Web content more accessible not just to users with disabilities but also to users in general. There have been two versions of WCAG, beginning with WCAG 1.0, which was developed in 1999, and an updated version, WCAG 2.0, which was released in 2008.

Voluntary standards can be sufficient in certain contexts, particularly where economic incentives align with the standards' goals. Reliance on voluntary compliance with Web site accessibility guidelines, however, has not resulted in equal access for persons with disabilities. *See, e.g.,* National Council on Disability, *The Need for Federal Legislation and Regulation Prohibiting Telecommunications and Information Services Discrimination* (Dec. 19, 2006), available at *http://www.ncd.gov/publications/2006/Dec282006* (last visited Apr. 13, 2016) (discussing how competitive market forces have not proven sufficient to provide individuals with disabilities access to telecommunications and information services). The WAI leadership has recognized this challenge and has stated that in order to improve and accelerate Web accessibility it is important to "communicat[e] the applicability of the ADA to the Web more clearly, with updated guidance * * * ." *Achieving the Promise of the Americans with Disabilities Act in the Digital Age—Current Issues, Challenges, and Opportunities: Hearing Before the Subcomm. on the Constitution, Civil Rights, and Civil Liberties, H. Comm. On the Judiciary,* 111th Cong. 35 (Apr. 22, 2010) (statement of Judy Brewer, Director, Web Accessibility Initiative at the W3C®) available at *http://judiciary.house.gov/_files/hearings/printers/111th/111-95_56070.PDF* (last visited Apr. 13, 2016).

Despite the availability of voluntary Web accessibility standards and the Department's clearly stated position that title II requires all services, programs, and activities of public entities, including those available on Web sites, to be accessible, individuals with disabilities continue to struggle to obtain access to the Web sites of public entities. As a result, the Department has addressed Web access in many agreements with State and local governments. Moreover, other Federal agencies have also taken enforcement action against public entities regarding the lack of access for persons with disabilities to their Web sites. In April 2013, for example, the Department of Labor cited the Florida Department of Economic Opportunity Office of Unemployment Compensation for violating Federal statutes, including title II of the ADA, for requiring unemployment compensation applicants to file claims online and complete an online skills assessment as part of the claims-filing process even though the State's Web site was inaccessible. *In re Miami Workers Ctr.,* CRC Complaint No. 12–FL–048 (Dep't Labor 2013) (initial determination), available at *http://nelp.3cdn.net/2c0ce3c2929a0ee4e1_wim6i5ynx.pdf* (last visited Apr. 13, 2016).

The Department believes that adopting Web accessibility standards would provide clarity to public entities regarding how to make accessible the services, programs, and activities they offer the public via their Web sites. Adopting specific Web accessibility standards to guide public entities in maintaining accessible Web sites would also provide individuals with disabilities with consistent and predictable access to the Web sites of public entities. As noted above, many services, programs, and activities that public entities offer on their Web sites have not been accessible to individuals with disabilities. Because Web sites can be accessed at any time, these services, programs, and activities are available to the public at their convenience. Accessible alternative means for obtaining access to services, programs, and activities offered on Web sites, such as a staffed telephone line, would need to afford individuals with disabilities equivalent access to such Web-based information and services (*i.e.,* 24 hours a day/7 days a week). As indicated in the 2003 guidance, the Department questions whether alternative means would be likely to provide an equal degree of access. As Web sites have become more interconnected, dynamic, and content heavy, it has become more difficult, if not impossible, for public entities to replicate by alternative means the services, programs, and activities offered on the Web. *Accessibility of State and Local Government Web sites to People with Disabilities,* available at *http://www.usdoj.gov/crt/ada/Websites2.htm* ("These alternatives, however, are unlikely to provide an equal degree of access in terms of hours of operation and the range of options and programs available."). The increasingly interconnected and dynamic nature of Web sites has allowed the public to easily and quickly partake in a public entity's programs, services, and activities via the Web. Individuals with disabilities—like other members of the public—should be able to equally engage with public entities' services, programs, and activities directly through the medium of the Web. Opportunities for such engagement, however, require that public entities' Web content be accessible to individuals with disabilities. These issues are also discussed in the 2010 ANPRM, *see* 75 FR 43460 (July 26, 2010).

After considering the comments that it received in response to its 2010 ANPRM, the Department has refined its proposal and is issuing this SANPRM to focus on the accessibility of Web information and services of State and local government entities and to seek further public comment.

II. Request for Public Comment

The Department is seeking comments in response to this SANPRM, including the proposed framework, definitions, requirements, and timeframes for compliance under consideration, and to the specific questions posed in this SANPRM. The Department is particularly interested in receiving comments from all those who have a stake in ensuring that the Web sites of public entities are accessible to people with disabilities or who would otherwise be affected by a regulation requiring Web site access. The Department appreciates the complexity and potential impact of this initiative and therefore also seeks input from experts in the field of computer science, programming, networking, assistive technology, and other related fields whose feedback and expertise will be critical in developing a workable framework for Web site access, which respects the unique characteristics of the Internet and its transformative impact on everyday life. In your comments, please refer to each question by number. Please provide additional information not addressed by the proposed questions if you believe it would be helpful in understanding the implications of imposing ADA regulatory requirements on the Web sites of State and local government entities.

A. The Meaning of "Web Content"

The Department is generally considering including within the scope of its proposed rule all Web content public entities make available to the public on their Web sites and Web pages, regardless of whether such Web content is viewed on desktop computers, notebook computers, smart phones, or other mobile devices. WCAG 2.0 defines Web content as "information and sensory experience to be communicated to the user by means of a user agent, including code or markup that defines the content's structure, presentation, and interactions." *See Web Content Accessibility Guidelines 2.0* (Dec. 2008), available at *http://www.w3.org/TR/WCAG/#glossary* (last visited Apr. 13, 2016). For any proposed rule, the Department would consider adding a definition for "Web content," which would be based on the WCAG 2.0's definition but would be slightly less technical with the intention that it could be more easily understood by the public generally. A proposed definition for "Web content" could look like the following:

> Information or sensory experience—including the encoding that defines the structure, presentation, and interactions—that is communicated to the user by a Web browser or other software. Examples of Web content include text, images, sounds, videos, controls, and animations.

The above definition of "Web content" attempts to describe the different types of information and experiences available on the Web. The definition of "Web content" also would include the encoding (*i.e.*, programming code) used to create the structure, presentation, or interactions of the information or experiences on Web pages that range from static Web pages (*e.g.*, Web pages with only textual information) to dynamic Web pages (*e.g.*, Web pages with live Web chats). Examples of programming languages used to create Web pages include Hypertext Markup Language (HTML), Cascading Style Sheets (CSS), Flash, and JavaScript.

The above definition of Web content would not, however, include a Web browser or other software that retrieves and interprets the programming code and displays it as a Web site or Web page. Web browsers are a vehicle for viewing Web content and are usually separate from the information, experiences, and encoding on a Web site. Typically, a person needs a Web browser to access the information or experiences available on the Web. A Web browser is the primary software on a desktop or notebook computer, or on a smart phone or other mobile device, which enables a person to view Web sites and Web pages. Common Web browsers used on desktop computers and mobile devices include Chrome, Firefox, Internet Explorer, Opera, and Safari. Web browsers retrieve and display different types of information and experiences available from Web sites and Web pages. Web browsers display the information and experiences by retrieving and interpreting the encoding—such as HTML—that is used to create Web sites and Web pages.

The definition of "Web content" also would not include other software, such as plug-ins, that help to retrieve and display information and experiences that are available on Web sites and Web pages of public entities. For example, when a person clicks on a PDF document or link on a Web page, Adobe Reader—which is a plug-in software—will open the PDF document either within the Web browser or directly in Adobe Reader, depending on the Web browser's settings. Similarly, other popular plug-ins, such as Adobe Flash Player, Apple QuickTime Player, and Microsoft Windows Media Player allow users to play audio, video, and animations. The fact that plug-ins are required to open the PDF document, audio file, or video file is not always apparent to the person viewing the PDF document, listening to the audio, or watching the video.

In sum, the Department is considering proposing a rule that would cover Web content available on public entities' Web sites and Web pages but that generally would not extend to most software, including Web browsers. The Department proposes a series of questions in section VI.B, however, regarding whether it should consider covering services, programs, and activities offered by public entities through mobile software applications (*see* section VI.B "Mobile Applications").

Question 1: Although the definition of "Web content" that the Department is considering proposing is based on the "Web Content" definition in WCAG 2.0, it is a less technical definition. Is the Department's definition under consideration in harmony with and does it capture accurately all that is contained in WCAG 2.0's "Web content" definition?

B. Access Requirements to Apply to Web sites and Web Content of Public Entities

1. Standards for Web Access

In its 2010 ANPRM, the Department asked for public comment about which accessibility standard it should apply to the Web sites of covered entities. The 2010 ANPRM discussed three potential accessibility standards to apply to Web sites of covered entities: (1) WCAG 2.0; (2) the Electronic and Information Technology Accessibility Standards, more commonly known as the section 508 standards; and (3) general performance-based standards. As explained below, the Department is considering proposing WCAG 2.0 Level AA as the accessibility standard that would apply to Web sites and Web content of title II entities.

Since 1994, the W3C® has been the principal international organization involved in developing protocols and guidelines for the Web. The W3C® develops a variety of technical standards and guidelines, including ones relating to privacy, internationalization of technology, and, relevant to this rulemaking, accessibility. The W3C®'s WAI has developed voluntary guidelines for Web accessibility, known as WCAG, to help Web developers create Web content that is accessible to individuals with disabilities. The first version of WCAG (hereinafter referred to as WCAG 1.0) was published in 1999. The most recent and updated version of WCAG (hereinafter referred to as WCAG 2.0) was published in December 2008, and is available at *http://www.w3.org/TR/2008/REC–WCAG20–20081211/* (last visited Apr. 13, 2016).

WCAG 2.0 has become the internationally recognized benchmark for Web accessibility. In October 2012, WCAG 2.0 was approved as an international standard by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Several nations, including Australia, Canada, France, Germany, Hong Kong, Japan, New Zealand, and South Korea, have either adopted WCAG 2.0 as their standard for Web accessibility or developed standards based on WCAG 2.0. Within the United States, some States, including Alaska, Georgia, Hawaii, and Minnesota, are also using WCAG 2.0 as their standard for Web accessibility. The Web accessibility standards in other States, such as California, Florida, Illinois, Maryland, New York, and Texas, are based on the section 508 standards (which are currently based on WCAG 1.0), and efforts are underway in at least one of these States to review and transition to WCAG 2.0.

WCAG 2.0 was designed to be "technology neutral" (*i.e.,* it does not rely on the use of specific Web technologies) in order to accommodate the constantly evolving Web environment and to be usable with current and future Web technologies. Thus, while WCAG 2.0 sets an improved level of accessibility and testability over WCAG 1.0, it also allows Web developers more flexibility and potential for innovation.

WCAG 2.0 contains four principles that provide the foundation for Web accessibility. Under these four principles, there are 12 guidelines setting forth basic goals to ensure accessibility of Web sites. For each guideline, testable success criteria (*i.e.,* requirements for Web accessibility that are measurable) are provided "to allow WCAG 2.0 to be used where requirements and conformance testing are necessary such as in design specification, purchasing, regulation and contractual agreements." *See WCAG 2.0 Layers of Guidance, Web Content Accessibility Guidelines 2.0* (Dec. 2008), available at *http://www.w3.org/TR/WCAG/#intro-layers-guidance* (last visited Apr. 13, 2016).

In order for a Web page to conform to WCAG 2.0, the Web page must satisfy all success criteria under one of the three levels of conformance: A, AA, or AAA. The three levels of conformance indicate a measure of accessibility. Level A, which is the minimum level of conformance, contains criteria that provide basic Web accessibility. Level AA, which is the intermediate level of conformance, includes all of the Level A criteria as well as enhanced criteria that provide more comprehensive Web accessibility. Level AAA, which is the maximum level of conformance, includes all Level A and Level AA criteria as well as additional criteria that can provide a more enriched user experience. At this time, the W3C® does not recommend that Level AAA conformance be required as a general policy for entire Web sites because it is not possible to satisfy all Level AAA criteria for some content. *See Understanding Requirement 1, Understanding WCAG 2.0: A Guide to Understanding and Implementing WCAG 2.0* (last revised Jan. 2012), available at *http://www.w3.org/TR/UNDERSTANDING-WCAG20/conformance.html#uc-conformance-requirements-head* (last visited Apr. 13, 2016).

The 2010 ANPRM asked the public to provide input on which of the three conformance levels the Department should adopt if it decided to use WCAG 2.0 as the standard for Web accessibility. Most of the comments the Department received overwhelmingly supported adopting Level AA conformance. Commenters emphasized that Level AA conformance has been widely recognized and accepted as providing an adequate level of Web accessibility without being too burdensome or expensive. Some commenters urged the Department to adopt Level A conformance under WCAG 2.0, stating that requiring any higher level of conformance would result in hardship for smaller entities because of their lack of resources and technical expertise. The commenters supporting the adoption of Level A conformance asserted that some Level AA criteria, such as the provision to caption all live-audio content in synchronized media, are expensive and technically difficult to implement. The W3C®, the creator of WCAG 2.0, submitted comments stating that the adoption of Level AA conformance is appropriate and necessary to ensure a sufficient level of accessibility for individuals with different kinds of disabilities and is feasible to implement for Web sites ranging from the most simple to the most complex. No commenters suggested that the Department adopt Level AAA in its entirety.

Based on its review of public comments and independent research, the Department is considering proposing WCAG 2.0 Level AA as the technical standard for public entity Web sites because it includes criteria that provide more comprehensive Web accessibility to individuals with disabilities—including those with visual, auditory, physical, speech, cognitive, developmental, learning, and neurological disabilities. In addition, Level AA conformance is widely used, indicating that it is generally feasible for Web developers to implement. Level A conformance does not include criteria for providing Web accessibility that some commenters generally considered important, such as minimum levels of contrast, text resizable up to 200 percent without loss of content, headings and labels, or visible keyboard focus (*e.g.,* a visible border showing keyboard navigation users the part of the Web page with which they are interacting).[1] Also, while Level AAA conformance provides a better and enriched user experience for individuals with disabilities, it is not possible to satisfy all Level AAA Success Criteria for some content. Therefore, the Department believes that Level AA conformance is the most appropriate standard.

Note that while WCAG 2.0 provides that for "Level AA conformance, the Web page [must] satisf[y] all the Level A and Level AA Success Criteria," individual Success Criteria in WCAG 2.0 are labeled only as Level A or Level AA. *See Conformance Requirements, Web Content Accessibility Guidelines 2.0* (Dec. 2008), available at *http://www.w3.org/TR/WCAG/#conformance-reqs* (last visited Apr. 13, 2016). A person reviewing individual requirements in WCAG 2.0, accordingly, may not understand that both Level A and Level AA Success Criteria must be met in order to attain Level AA. Therefore, for clarity, the Department is considering that any specific regulatory text it proposes regarding compliance with WCAG 2.0 Level AA should provide that covered entities must comply with both Level A and Level AA Success Criteria and Conformance Requirements specified in WCAG 2.0.

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[1] W3C®, *Focus Visible: Understanding SC 2.4.7.,* available at *https://www.w3.org/TR/UNDERSTANDING–WCAG20/navigation-mechanisms-focus-visible.html* (last visited Apr. 13, 2016).

Adoption of WCAG 2.0 Level AA would make the ADA requirements consistent with the standard that has been most widely accepted internationally. As noted earlier, several nations have selected Level AA conformance under WCAG 2.0 as their standard for Web accessibility. Additionally, in 2012, the European Commission issued a proposal for member countries to adopt Level AA conformance under WCAG 2.0 as the accessibility standard for public sector Web sites, available at *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0721:FIN:EN:PDF* (last visited Apr. 13, 2016). The Web sites of Federal agencies that are governed by section 508 may soon also need to comply with WCAG 2.0. The U.S. Access Board (Access Board) has proposed to update and revise the section 508 standards by adopting the Level AA conformance requirements under WCAG 2.0. *See* 80 FR 10880 (Feb. 27, 2015); 76 FR 76640 (Dec. 8, 2011); 75 FR 13457 (Mar. 22, 2010).

The Department also considered whether it should propose adoption of the current section 508 standards instead of WCAG 2.0. The 2010 ANPRM sought public comment on this question. Section 508 of the Rehabilitation Act requires the Federal government to ensure that the electronic and information technology that it develops, procures, maintains, or uses—including Web sites—is accessible to persons with disabilities. *See* 29 U.S.C. 794(d). In 2000, the Access Board adopted and published the section 508 standards, 36 CFR part 1194, available at *http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards/section-508-standards* (last visited Apr. 13, 2016), to implement section 508. The section 508 standards, among other things, provide specific technical requirements to ensure that Federal government Web sites are accessible to individuals with disabilities. These technical requirements for Web accessibility are based on WCAG 1.0. Public commenters on the 2010 ANPRM overwhelmingly supported the Department's adoption of WCAG 2.0 over the current section 508 standards. Commenters emphasized that because the Web accessibility requirements in the current section 508 standards are based on the almost 14-year-old WCAG 1.0, they are outdated and inappropriate to address the evolving and increasingly dynamic Web environment. The Department agrees that since WCAG 1.0 and the section 508 standards were issued, Web technologies and online services have evolved and changed, and, thus, the Department does not believe that either one would be the appropriate standard for any title II ADA Web accessibility requirements. By contrast, WCAG 2.0 provides an improved level of accessibility and testability. Also, unlike WCAG 1.0, WCAG 2.0 has been designed to be technology neutral to provide Web developers more flexibility to address accessibility of current as well as future Web technologies. In addition, as mentioned previously, the Department is aware that the Access Board issued a recent NPRM in 2015 and two ANPRMs—one in 2010 and another in 2011—proposing to update and revise the section 508 standards by adopting WCAG 2.0 as the standard for Web accessibility. 80 FR 10880 (Feb. 27, 2015); 76 FR 76640 (Dec. 08, 2011); 75 FR 13457 (Mar. 22, 2010).

The Department's 2010 ANPRM also sought public comment on whether the Department should adopt performance standards instead of specific technical standards for accessibility of Web sites. Performance standards establish general expectations or goals for Web accessibility and allow for compliance via a variety of unspecified methods and means. While some commenters supported the adoption of performance standards for Web accessibility, pointing out that they provide greater flexibility in ensuring accessibility as Web technologies change, a vast majority of commenters supported the adoption of WCAG 2.0 instead. The majority of commenters stressed that performance standards are likely too vague and subjective and would prove insufficient in providing consistent and testable requirements for Web accessibility. Several commenters who supported the adoption of WCAG 2.0 also noted that, similar to a performance standard, WCAG 2.0 has been designed to allow for flexibility and innovation in the evolving Web environment. The Department recognizes the importance of adopting a standard for Web accessibility that provides not only specific and testable requirements, but also sufficient flexibility to develop accessibility solutions for new Web technologies. The Department believes that WCAG 2.0 achieves this balance because it provides flexibility similar to a performance standard, but also provides more clarity, consistency, and objectivity. Using WCAG 2.0 would also enable public entities to know precisely what is expected of them under title II, which may be of particular benefit to jurisdictions with less technological experience. It would also harmonize with the requirements adopted by certain other nations, some State and local governments in the U.S., and with the standard proposed by the U.S. Access Board that would apply to Federal agency Web sites. Thus, the Department is considering proposing that public entities comply with WCAG 2.0 Level AA.

Question 2: Are there other issues or concerns that the Department should consider regarding the accessibility standard—WCAG 2.0 Level A and Level AA Success Criteria and Conformance Requirements—the Department is considering applying to Web sites and Web content of public entities? Please provide as much detail as possible in your response.

2. Timeframe for Compliance

The 2010 ANPRM asked for public comment regarding the effective date of compliance with any Web accessibility requirements the Department would adopt. Comments regarding the compliance date were extremely varied—ranging from requiring compliance upon publication to allowing a five-year window for compliance—with no clear consensus favored. Many of the comments advocating for shorter timeframes came from individuals with disabilities or disability advocacy organizations. These commenters argued that Web accessibility has long been required by the ADA and that an extended deadline for compliance rewards entities that have not made efforts to make their Web sites accessible. A similar number of commenters responded asking for longer timeframes to comply. Commenters representing public entities were particularly concerned about shorter compliance deadlines, often citing budgets and staffing as major limitations. Many public entities stated that they lack qualified personnel to implement Web accessibility requirements. The commenters stated that in addition to needing time to implement the changes to their Web sites, they also need time to train staff or contract with professionals who are proficient in developing accessible Web sites.

Despite the absence of a regulation, many public entities have some familiarity with Web accessibility. For over a decade, the Department has provided technical assistance materials, and engaged in concerted enforcement efforts, that specifically have addressed Web accessibility.[2] Additionally, while not all covered entities have adopted WCAG 2.0 Level AA, it is likely that there is some degree of familiarity with that standard in the regulated community, which may help mitigate the time needed for compliance. Therefore, the Department is considering a two-year implementation timeframe for most public entities in an effort to balance the importance of accessibility for individuals with disabilities with the resource challenges faced by public entities. The Department is considering the following proposal to address specific standards and timeframes for compliance:

> Effective two years from the publication of this rule in final form, a public entity shall ensure that the Web sites and Web content it makes available to members of the public comply with Level A and Level AA Success Criteria and Conformance Requirements specified in 2008 WCAG 2.0, except for Success Criterion 1.2.4 on live-audio content in synchronized media,[3] unless the public entity can demonstrate that compliance with this section would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens.

Under such a proposal, public entities would have two years after the publication of a final rule to make their Web sites and Web content accessible in conformance with WCAG 2.0 Level AA, unless compliance with the requirements would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens. (The limitations on a public entity's obligation to comply with the proposed requirements are discussed in more detail in section V. "Compliance Limitations and Other Duties" below.)

Question 3: Does an effective date of two years after the publication of a final rule strike an appropriate balance of stakeholder interests? Why or why not? Should the Department consider a shorter or longer effective date? If so, what should those timeframes be and why? Please provide support for your view. Should the Department consider different approaches for phasing in compliance? For example, should the Department consider permitting public entities to make certain Web pages (e.g., most frequently used or necessary to participate in the public entity's service, program, or activity) compliant by an initial deadline, and other Web pages compliant by a later deadline? If so, how should the Department define the Web pages that would be made accessible first, and what timeframes should the Department consider? Please provide support for your view.

Question 4: Some 2010 ANPRM commenters expressed concern that there is likely to be a shortage of professionals who are proficient in Web accessibility to assist covered entities in bringing their Web sites into compliance. Please provide any data that the Department should consider that supports your view.

3. Captions for Live-Audio Content in Synchronized Media

Level AA Success Criterion 1.2.4 under WCAG 2.0 requires synchronized captions for all live-audio content in synchronized media. The intent of Success Criterion 1.2.4 is to "enable people who are deaf or hard of hearing to watch *real-time* presentations. Captions provide the part of the content available via the audio track. Captions not only include dialogue, but also identify who is speaking and notate sound effects and other significant audio." *See Captions (Live), Understanding WCAG 2.0: A Guide to Understanding and Implementing WCAG 2.0* (last revised Jan. 2012), available at *http://www.w3.org/TR/UNDERSTANDING-WCAG20/media-equiv-real-time-captions.html* (last visited Apr. 13, 2016) (emphasis in original).

Because of the added cost of, and the lack of mature technologies for, providing real-time captions for live performances or events presented on the Web, some countries that have adopted WCAG 2.0 Level AA as their standards for Web accessibility, such as Canada and New Zealand, have specifically exempted the requirement for captioning of live-audio content in synchronized media. Also, as mentioned previously, several commenters urged the Department to not adopt Level AA conformance under WCAG 2.0 because of their concern that providing synchronized captions for all live-audio content in synchronized media on the Web would be technically difficult to implement.

The Department recognizes commenters' concerns that providing real-time captions for live performances or events may be technically difficult to implement and may create additional costs and burdens for public entities. However, the Department also recognizes that technologies used to provide real-time captions for Web content are improving and that covered entities are increasingly providing live Webcasts (*i.e.*, broadcasts of live performances or events on the Web) of public hearings and committee meetings, the majority of which are not accessible to individuals with disabilities. In order for individuals with disabilities to participate in civic life more fully, public entities need to provide real-time captions for public hearings or committee meetings they broadcast on the Web as technology improves and providing captions becomes easier. Still, the information gathered from public comments and independent research suggests that public entities may need more time to make this type of Web content accessible. Accordingly, the Department is considering a longer compliance schedule for public entities to comply with the WCAG 2.0 Level AA conformance requirements to provide captions for live-audio content in synchronized media on Web sites and seeks public input on how it should frame those proposed requirements. The Department is considering the following proposal for captions for live-audio content in synchronized media:

> Effective three years from the publication of this final rule, a public entity shall ensure that live-audio content in synchronized media it makes available to members of the public complies with Level AA Success Criteria and Conformance Requirements specified in 2008 WCAG 2.0, unless the public entity can demonstrate that compliance with this section would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens.

Question 5: Is there technology available now that would allow public entities to efficiently and effectively provide captioning of live-audio content in synchronized media in compliance with WCAG 2.0 Level AA conformance? If so, what is the technology and how

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[2] *See, e.g., The ADA Best Practices Tool Kit for State and Local Governments* (July 26, 2007), available at *http://www.ada.gov/pcatoolkit/toolkitmain.htm; Chapter 5: Web site Accessibility under Title II of the ADA* (May 7, 2007), available at *http://www.ada.gov/pcatoolkit/ch5_toolkit.pdf; Chapter 5 Addendum: Title II Checklist (Web site Accessibility)* (May 4, 2007), available at *http://www.ada.gov/pcatoolkit/ch5_chklist.pdf; Cities and Counties: First Steps toward Solving Common ADA Problems*, available at *http://www.ada.gov/civiccommonprobs.htm; Accessibility of State and Local Government Web sites to People with Disabilities* (June 2003), available at *http://www.usdoj.gov/crt/ada/Web sites2.htm;* Settlement Agreement Between the United States and Pennington County, South Dakota, Under the Americans with Disabilities Act (effective June 1, 2015), available at *http://www.ada.gov/pennington_co/pennington_sa.html.*

[3] Live-audio content in synchronized media, addressed in Level AA Success Criterion 1.2.4, is discussed in section II.B.3. "Captions for Live-Audio Content in Synchronized Media" below.

much does it cost? If public entities currently provide captioning for live-audio content, what method, process, or technology do they use to provide the captions? If such technology is not currently available, when is it likely to become available?

Question 6: What are the availability and the cost of hiring and using trained professionals who could provide captions for live-audio content in synchronized media? What are the additional costs associated with producing captions for live-audio content in synchronized media, such as the technological components to ensuring that the captions are visible on the Web site and are synchronized with the live-audio content?

Question 7: Should the Department consider a shorter or longer effective date for the captioning of live-audio content in synchronized media requirement, or defer this requirement until effective and efficient technology is available? Please provide detailed data and information for the Department to consider in your response.

4. Equivalent Facilitation

The Department recognizes that a public entity should be permitted to use designs, products, or technologies as alternatives to those prescribed for any Web accessibility requirements, provided that such alternatives result in substantially equivalent or greater accessibility and usability. The Department is considering including a provision in a proposed Web access rule that addresses this principle, which is known as equivalent facilitation. The 1991 and 2010 ADA Standards for Accessible Design both contain a similar equivalent facilitation provision. The purpose of allowing for equivalent facilitation is to encourage flexibility and innovation by covered entities while still ensuring substantially equivalent or greater accessibility and usability. The Department believes, however, the responsibility for demonstrating equivalent facilitation rests with the covered entity.

Question 8: Are there any existing designs, products, or technologies (whether individually or in combination with others) that would result in accessibility and usability that is either substantially equivalent to or greater than WCAG 2.0 Level AA?

Question 9: Are there any issues or concerns that the Department should consider in determining how a covered entity would demonstrate equivalent facilitation?

C. Alternative Requirements

1. Small Public Entities

The Department is also interested in exploring and receiving public comment about whether to consider proposing alternate conformance levels, compliance date requirements, or other methods to minimize any significant economic impact on small public entities. The discussion in this section provides the Department's thinking regarding potential ways to minimize any significant economic impact on small entities. However, the Department is open to other alternatives for achieving this purpose and that satisfy the requirements and purposes of title II of the Americans with Disabilities Act.

For the purpose of this rulemaking, a "small public entity" is one that qualifies as a "small governmental jurisdiction" under the Regulatory Flexibility Act of 1980 (RFA), which defines the term to mean "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand * * *"). 5 U.S.C. 601(5). In order to make the distinction between the population sizes of public entities clear for the purposes of a rulemaking, the Department is considering proposing that the population of a public entity should be determined by reference to the total general population of the jurisdiction as calculated by the U.S. Census Bureau, not the population that is eligible for or that takes advantage of the public entity's specific services. For example, a county school district in a county with a population of 60,000 would not be considered a small public entity regardless of the number of students enrolled in or eligible for services. As another example, individual county schools also would not be considered small public entities if they are components of a county government that has a population of over 50,000 (*i.e.,* the individual county schools are not separate legal entities). While the individual county school in this example may create and maintain a Web site, like in any other matter involving that school, it is a county entity that is ultimately legally responsible for what happens in the individual school.

In the 2010 ANPRM, the Department solicited public comment on whether it should consider different compliance requirements or a different timetable for small entities in order to reduce the impact on them as required by the RFA and Executive Order 13272. *See* 75 FR 43460, 43467 (July 26, 2010). Many disability organizations and individual commenters did not support having a different timetable or different accessibility requirements for smaller entities, stating that such a proposal would be confusing because people with disabilities would be uncertain about which Web sites they visit should be accessible and by when. Those commenters further emphasized that access to Web content of small entities is important and that many small entities have smaller Web sites with fewer Web pages, which would make compliance easier and therefore require fewer resources. Commenters opposing different timetables or accessibility requirements for smaller entities also noted that small entities are protected from excessive burdens deriving from rigorous compliance dates or stringent accessibility standards by the ADA's undue burden compliance limitations.

Many commenters, especially Web developers and those representing covered entities, stated that compliance in incremental timeframes would be helpful in allowing covered entities—especially smaller ones—to allocate resources (both financial and personnel) to bring their Web sites into compliance. These commenters noted that many small entities do not have a dedicated Web master or staff. Even when these small entities develop or maintain their own Web sites, commenters stated that they often do so with staff or volunteers who have only a cursory knowledge of Web design and merely use manufactured Web templates or software, which may not be accessible, to create Web pages. Additionally, even when small entities do use outside help, a few commenters expressed concern that there is likely to be a shortage of professionals who are proficient in Web accessibility to assist all covered entities in bringing their Web sites into compliance all at once. Some commenters also expressed concern that smaller entities would need to take down their Web sites because they would not be able to comply with the accessibility requirements. Accordingly, the Department is interested in receiving comment on whether "small public entities"—again those with a population of 50,000 or less—should have an additional year (*i.e.,* three years total) or other expanded timeframe to comply with the specific Web requirements the Department proposes.

In addition to a longer timeline for compliance, the Department is considering whether to propose applying WCAG 2.0 Level A to certain very small public entities. As mentioned previously, in the 2010 ANPRM the Department asked for public comment regarding what compliance alternatives the Department should consider for small public entities. Comments received in response to the 2010 ANPRM indicate that many small public entities should be able to comply with Level A and Level AA Success Criteria and Conformance Requirements specified in WCAG 2.0. However, the Department is interested in public comment regarding whether it should consider applying a different WCAG 2.0 conformance level to very small public entities (*e.g.*, entities with populations below 2,500, 1,000, etc.) that may initially face more technical and resource challenges in complying than larger public entities. The Department seeks public comment on whether it should consider requiring WCAG 2.0 Level A conformance for very small public entities. In addition, the Department is interested in whether there are certain population thresholds within the category of small public entities or other criteria that should be used to define these very small public entities. Also, the Department is interested in public comment on whether there is a certain subset of very small public entities (*e.g.*, entities with populations below 500, 250, etc.) for which compliance with even Level A would be too burdensome and, thus, the Department should consider deferring compliance with WCAG 2.0 altogether at this time for those entities.

WCAG 2.0 Level A does not include the requirement to provide captioning of live-audio content in synchronized media. However, were the Department to require WCAG 2.0 Level AA conformance for very small public entities, the Department is considering whether the requirement to provide captioning of live-audio content in synchronized media should be deferred for very small public entities. Also, the Department is considering whether the requirement to provide captioning of live-audio content in synchronized media should be deferred for all small public entities at this time.

Question 10: Would the Department be correct to adopt the RFA's definition for a "small governmental jurisdiction" (i.e., governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000) as its population threshold for small public entities? Are there other definitions for "small governmental jurisdiction" the Department should consider using to define the population threshold for small public entities for purposes of this rulemaking? Please provide as much information as possible, including any supporting data for your views.

Question 11: Are there technical and resource challenges that smaller entities might face in meeting Level AA conformance? At what level are small public entities currently providing accessibility on their Web sites? Do small public entities have internal staff to modify their Web sites, or do they utilize outside consulting staff to modify and maintain their Web sites? Are small public entities facing budget constraints that may impair their ability to comply with this regulation?

Question 12: Are there other issues or considerations regarding the accessibility standard—WCAG 2.0 Level A Success Criteria and Conformance Requirements— that the Department is considering applying to Web sites and Web content of very small public entities that the Department should consider? Please provide as much detail as possible in your response.

Question 13: If the Department were to apply a lower compliance standard to very small public entities (WCAG 2.0 Level A), what would be the appropriate population threshold or other appropriate criteria for defining that category? Should the Department consider factors other than population size, such as annual budget, when establishing different or tiered compliance requirements? If so, what should those factors be, why are they more appropriate than population size, and how should they be used to determine regulatory requirements? What would be the consequences for individuals with disabilities if the Department applied a lower compliance standard, WCAG 2.0 Level A, to very small public entities?

Question 14: Would applying to very small public entities an effective date of three years after the publication of the final rule strike an appropriate balance of stakeholder interests? Why or why not? Should the Department consider a shorter or longer effective date for very small public entities? Please provide specific examples or data in support of your response.

Question 15: Should the Department defer compliance with WCAG 2.0 altogether for a subset of very small public entities? Why or why not? If so, what would be the appropriate population threshold or other appropriate criteria for defining that subset of very small public entities? Should the Department consider factors other than population size, such as annual budget, when establishing the subset of public entities subject to deferral? If so, what should those factors be, why are they more appropriate than population size, and how should they be used to determine regulatory requirements? What would be the consequences to individuals with disabilities if the Department deferred compliance with WCAG 2.0 for a subset of very small public entities?

Question 16: If the Department were not to apply a lower compliance standard to very small public entities (WCAG 2.0 Level A), should the Department consider a deferral of the requirement to provide captioning of live-audio content in synchronized media for very small public entities? Additionally, should the Department consider a deferral of the requirement to provide captioning of live-audio content in synchronized media for all small public entities? Why or why not?

2. Special Districts

The Department is also interested in gathering information and comments on how it should frame the requirements for Web access for special district governments. For the purposes of the Department's rulemaking, a special district government is a public entity—other than a county, municipality, township, or independent school district—authorized by State law to provide one function or a limited number of designated functions with sufficient administrative and fiscal autonomy to qualify as a separate government and with a population that is not calculated by the United States Census Bureau in the most recent decennial Census or Small Area Income and Poverty Estimates.[4] The Department is considering whether special district governments should be required to meet a lower conformance standard, WCAG 2.0 Level A, and be allotted three years for compliance or another extended compliance date.

A lower conformance standard and a longer timeframe for compliance for special district governments may be appropriate for two reasons. First, because the U.S. Census Bureau does not provide population estimates for special district governments, it would be difficult for these limited-purpose public entities to obtain population estimates that are objective and reliable to determine their duties under any proposed rule that differentiates among public entities based on population size. While some special district governments may estimate their total populations, these entities may use varying methodologies to calculate population estimations leading to possible confusion and inconsistency in the application of the proposed accessibility requirements. Second, special district governments are generally formed to perform a single function or a very limited number of functions (*e.g.*, provide mosquito abatement or water and sewer services) and have more limited or specialized budgets. Therefore, the Department is interested in gathering information and comments regarding whether special district governments should comply with WCAG 2.0 Level A instead of Level AA. The Department is also interested in receiving comment on whether an extended date for compliance of three years for special district governments is warranted and necessary.

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[4] *See* U.S. Census Bureau, *Lists and Structure of Governments: Population of Interest—Special Districts*, available at *https://www.census.gov/govs/go/special_district_governments.html* (last visited Apr. 13, 2016).

Question 17: Are there technical and resource challenges that special districts might face in meeting Level AA conformance? At what level are special districts currently providing accessibility on their Web sites? Do special districts have internal staff to modify their Web sites, or do they utilize outside consulting staff to modify and maintain their Web sites? Are special districts facing budget constraints that may impair their ability to comply with a proposed regulation requiring compliance with Level AA?

Question 18: Are there other issues or considerations regarding the accessibility standard—WCAG 2.0 Level A Success Criteria and Conformance Requirements— that the Department is considering applying to Web sites and Web content of special district governments that the Department should consider? Please provide as much detail as possible in your response.

Question 19: Does the description of special district governments above make clear which public entities are captured by that category? Is there any additional information on calculating the populations of special district governments that the Department should consider?

III. Exceptions to the Web Access Requirements

In the 2010 ANPRM, the Department requested public comment on whether it should adopt certain coverage limitations when it develops its proposed ADA Web regulations. The Department was particularly interested in hearing about the challenges covered entities might face in making existing Web content accessible, whether it should except from any rule Web content posted by third parties, and whether it should except content on Web sites linked from the Web sites of public entities. Commenters that supported providing exceptions suggested that materials on the public entities' Web sites prior to the effective date of a regulation should not be subject to a Web access rule, as long as the materials are not subsequently modified or updated after any regulation becomes effective. These commenters believed that it would be burdensome to require public agencies to retroactively make all documents on their Web site accessible, noting that many of the outdated documents were hundreds of pages long and were scanned images. Several commenters requested that the Department except from any Web access rule links on public entities' Web sites to other Web sites unless either the public entities operate or control the other Web site or access to the linked content is important or necessary to participate in the public entities' services. Many commenters supported exceptions for Web content posted by third parties on public entities' Web sites and at least one commenter suggested that where practicable, public entities should make and publicize the availability of alternative accessible means for accessing the third-party Web content. On the other hand, a small number of comments—mostly from advocacy groups and private citizens—suggested that the title II regulation should not include any exceptions because the undue administrative and financial burdens compliance limitations would protect public entities from overly burdensome requirements resulting from such a regulation. Finally, a number of commenters urged the Department to require public entities to develop and deploy Web platforms (*i.e.*, a Web site framework with services, tools, and interfaces that enable users to interact with a Web site) that are accessible so that third parties would have the ability to make the Web content they post on public entities' Web sites accessible. After consideration of these comments and after conducting independent research, as described in more detail below, the Department is currently of the view that some exceptions to any Web access standards may be warranted and should therefore be part of any Department rulemaking.

At this juncture, the Department is considering a number of categories of Web content for potential exceptions: (1) Archived Web content; (2) certain preexisting conventional electronic documents; (3) third-party Web content linked from a public entity's Web site; and (4) certain Web content posted by third parties on a public entity's Web site.

A. Archived Web Content

The Web sites of many public entities often include a significant amount of archived Web content, which may contain information that is outdated, superfluous, or replicated elsewhere. Generally, this historic information is of interest to only a small segment of the general population. Still, the information may be of interest to some members of the public, including some individuals with disabilities, who are conducting research or are otherwise interested in these historic documents. The Department is concerned, however, that public entities would need to expend considerable resources to retroactively make accessible the large quantity of historic information available on public entities' Web sites. Thus, the Department believes providing an exception from the Web access requirements for Web content that meets a definition it is considering proposing for "archived Web content" is appropriate. A proposed definition of "archived Web content" may look like the following:

> Archived Web content means Web content that: (1) Is maintained exclusively for reference, research, or recordkeeping; (2) is not altered or updated after the date of archiving; and (3) is organized and stored in a dedicated area or areas clearly identified as being archived.

Under the proposal presently under consideration by the Department, in order for archived Web content to be excepted from the Web access requirements of any proposed rule, all three prongs of the definition would have to be satisfied.

An archived Web content exception would allow public entities to keep and maintain historic Web content, while utilizing their resources to make accessible the many current and up-to-date materials that all citizens need to access for existing public services or to participate in civic life. As discussed below, despite any exception the Department might propose regarding archived Web content, individual requests for access to these excepted documents would still need to be addressed on a case-by-case basis in order to ensure that individuals with disabilities are able to receive the benefits or services of the public entity's archived Web content through other effective means. Under title II of the ADA, it is the responsibility of the public entity to make these documents accessible to individuals with disabilities, *see generally,* 42 U.S.C. 12132 and 28 CFR 35.160, and, "[i]n order to be effective, auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.'' 28 CFR 35.160(b)(2).

Question 20: Is the definition the Department is considering for archived Web content appropriate?

Question 21: Does the archived Web content definition and exception under consideration take into account how public entities manage outdated content on their Web sites? How often do individuals seek access to such documents and how long would it take public entities to provide these documents in an accessible format? Are there other issues that the Department should consider in formulating an archived Web content definition or an exception for archived materials on Web sites of public entities?

B. Preexisting Conventional Electronic Documents

The Department is considering excepting from any Web access rule, conventional electronic documents (*e.g.*, Microsoft Word documents) that exist on public entities' Web sites prior to the compliance date of any proposed rule (preexisting conventional electronic documents). In the past, documents created by or for a public entity were only available in traditional paper format; however, today most documents are created electronically via word processor software, such as Corel WordPerfect or Microsoft Word, or spreadsheet software, such as Corel Quattro Pro or Microsoft Excel. The Department's research indicates that most Web sites of public entities contain large amounts of current electronic documents that are intended to be used by members of the public in either an electronic form or as printed output, which are not suitable to be archived. The types of electronic documents can range from a single-page meeting notice containing only text to a comprehensive report containing text, images, charts, graphs, and maps. The majority of these electronic documents are in Adobe PDF format, but many electronic documents are formatted as word processor files (*e.g.*, Corel WordPerfect or Microsoft Word files), presentation files (*e.g.*, Apple Keynote or Microsoft PowerPoint files), spreadsheet files (*e.g.*, Corel Quattro Pro or Microsoft Excel files), and database files (*e.g.*, FileMaker Pro or Microsoft Access files). A proposed definition of ''conventional electronic documents'' may look like the following:

> Conventional electronic documents means electronic files available on a public entity's Web site that are in the following electronic file formats: portable document file (PDF) formats, word processor file formats, presentation file formats, spreadsheet file formats, and database file formats.

Because of the substantial number of conventional electronic documents on public entities' Web sites, and because of the difficulty of remediating complex types of information and data to make them accessible after-the-fact, the Department is considering a proposal to except certain preexisting conventional electronic documents from the Web access requirements. The Department is considering such an exception because it believes covered entities should focus their limited personnel and financial resources on developing new conventional electronic documents that are accessible and remediating existing electronic documents that are used by members of the public to apply for or gain access to the public entity's services, programs, or activities. The Department believes this approach may reduce the burdens on covered entities but still provide Web access to key documents. An exception for ''preexisting conventional electronic documents'' could then provide the following:

> Conventional electronic documents created by or for a public entity that are available on a public entity's Web site before the date the public entity is required to comply with this rule are not required to comply with the Web access standards, unless such documents are to be used by members of the public to apply for, gain access to, or participate in a public entity's services, programs, or activities.

Under such a proposal, the Department would anticipate requiring any preexisting document to be used by members of the public to apply for or gain access to the public entity's services, programs, or activities, including documents that provide instructions or guidance, would also need to be made accessible. For example, a public entity would not only need to make an application for a business license accessible, but it would also need to make accessible other materials that may be needed to obtain the license, complete the application, understand the process, or otherwise take part in the program. Accordingly, documents necessary to understand the process of obtaining the business license, such as business license application instructions, manuals, sample knowledge tests, and guides, such as ''Questions and Answers'' documents, would also be required to be accessible under such an exception. However, the Department believes that under such a proposal, if the public entity's Web site has the same information contained in multiple conventional electronic documents, the Department would expect that the public entity should only be required to ensure that a single complete set of instructions or guidance be available in an accessible format on the Web.

Question 22: Would such a definition and exception under consideration make clear the types of documents needed to apply for or gain access to services, programs, or activities? If some versions of documents are accessible and others are not, should the Department require that accessible documents be labeled as such? Are there other issues that the Department should take into consideration with regard to a proposed exception for conventional electronic documents?

C. Third-Party Web Content

The Department received a variety of comments regarding whether or not covered entities should be responsible for ensuring that third-party Web content and Web content public entities link to is accessible. For purposes of the proposals under consideration herein, ''third party'' refers to someone other than the public entity. Many commenters maintained that covered entities cannot be held accountable for third-party content on their Web sites because many entities do not control such content. A number of commenters also suggested that public entities be responsible for providing a platform that would allow users to post accessible content, but the public entities should not be responsible for guaranteeing the accessibility of the resulting user-generated content. Several commenters suggested that covered entities should not be responsible for third-party content and links unless they are necessary for individuals to access the services, programs, or activities of the public entities. A number of commenters expressed the view, however, that covered entities should be responsible for all third-party content. These commenters stated that the boundaries between Web content generated by a covered entity and a third party are often difficult to discern and cited the undue burden defense as a factor favoring coverage of third-party content. Additionally, these commenters took the position that excluding the Web content of these third parties was a ''loophole'' to providing full access and that covered entities must be responsible for the content on their Web site, regardless of its origin.

After considering these comments, the Department is considering proposing certain limited exceptions related to third-party content. It is important to note, however, that even if the Department were to except Web content posted by third parties on public entities' Web sites, the Department is considering proposing that public entities would still be responsible for ensuring that the platforms they provide for posting third-party Web content comply with any Web access rule.

1. Linked Third-Party Web Content

Many public entities' Web sites include links to other Web sites that contain information or resources in the community offered by third parties that are not affiliated with the public entity. Clicking on one of these links will take an individual away from the public entity's Web site and send the individual to the Web site of a third party. Typically, the public entity has no responsibility for the Web content or the operation of the third party's Web site. The Department is considering proposing an exception to a Web access rule so that a public entity would not be responsible for the accessibility of a third-party Web site or Web content linked from the public entity's Web site unless the public entity uses the third-party Web sites or Web content to allow members of the public to participate in or benefit from its services, programs, or activities. A proposed exception may look like the following:

> Third-party Web content linked from the public entity's Web site is not required to comply with the Web access standards unless the public entity uses the third-party Web site or Web content to allow members of the public to participate in or benefit from the public entity's services, programs, or activities.

Such an exception generally would allow public entities to provide relevant links to third-party Web sites or Web content that may be helpful without making them liable for the third party's Web content. However, the Department's title II regulation prohibits discrimination in the provision of any aid, benefit, or service provided by public entities directly or through contractual, licensing, or other arrangements. *See generally* 28 CFR 35.130(b)(1). Therefore, if a public entity uses the third-party Web site or Web content to allow members of the public to participate in or benefit from its services, programs, or activities, under any exception the Department may propose the public entity would be required to use third-party Web sites or Web content that comply with the Web access requirements of a final rule. Thus, a public entity that uses online payment processing services offered by a third party to accept the payment of fees, parking tickets, or taxes would be required to ensure that the third-party Web site and Web content complies with the Web access requirements. Similarly, if a public entity contracts or otherwise uses a third party to process applications for benefits, to sign up for classes, or to attend programs the public entity offers, the public entity would be required to ensure that the third party's Web site and Web content complies with the Web access rule. On the other hand, if a public entity provides a link to third-party Web content for informational or resource purposes only, then access by constituents is not required in order to participate in the public entity's services, programs, or activities, and the linked third-party Web content would not be required to be accessible.

Question 23: Are there additional issues that the Department should take into consideration with regard to linked third-party Web content? Has the Department made clear which linked third-party Web content it is considering covering and which linked third-party Web content the Department is considering excepting from coverage under a proposed rule? Why or why not?

2. Web Content Posted by a Third Party

The Department is considering generally excepting Web content posted by third parties on public entities' Web sites from compliance with WCAG 2.0 Level AA. However, the Department is considering requiring Web content posted by a third party that is essential for engaging in civic participation to comply with WCAG 2.0 Level AA.

The basis for this exception is that a public entity generally does not have control over the volume or substance of content posted by a third party on the public entity's Web site. To the extent that any content is reviewed by the public entity before it is posted, such review often is cursory or limited to automated pre-screening to prevent fraud, abusive language, or spamming. Public entities may not even be aware of when third parties post content on the public entities' Web sites. Where the posting of third-party Web content occurs in such an automated fashion, without notice to the public entity, the public entity may lack the practical capacity under these circumstances to make such material accessible.

The Department believes, however, that there are times when access to content posted by third parties on a public entity's Web site may be so essential for engaging in civic participation that the public entity should be required to make the Web content accessible. An example of third-party content which the Department would consider essential to engaging in civic participation is when a State seeks formal public comment on a proposed regulation and those comments are posted on the State Web site. Often the period for public comment is time sensitive, transparency is crucial, and a State will review and consider all such comments in finalizing its regulation. As such, it is vitally important that individuals with disabilities have access to that Web content, whether for framing their own comments, raising important points, reviewing and responding to comments posted by others, or evaluating the basis for the State's ultimate decision.

The Department notes that Web content created by a third party that a public entity decides to post itself would still be subject to WCAG 2.0 Level AA. The Department believes that a public entity should be responsible for Web content that it posts on its own initiative, even if the content is originally created or authored by a third party. In addition, if the Department were to except Web content posted by third parties as above, such an exception would provide public entities with a greater ability to direct their resources toward ensuring that the Web content the public entities themselves make available to the public is accessible.

Question 24: The Department intends the phrase "content posted by a third party on a public entity's Web site" to mean content that a third party creates and elects to make available on the public entity's Web site. Does the Department's use of the term "posted" in this context create confusion, and if so, is there another term that would be more appropriate for purposes of this exception?

Question 25: The Department requests public comment on whether the Department's rule should except from coverage almost all Web content posted by third parties on public entities' Web sites. The Department is also interested in obtaining information about what type of Web content is posted by third parties on Web sites of public entities (e.g., whether it contains only text, or includes images, videos, audio content, and other forms of media)?

Question 26: How much content is posted by third parties on public entities' Web sites and how frequently? Please provide as much information as possible, including any supporting data.

Question 27: To what extent are public entities on notice of postings by third parties on their Web sites? To what extent do public entities affirmatively decide what, or how much, third-party Web content can be posted on their Web sites? If public entities do affirmatively decide what, or how much, third-party

Web content to post on their Web sites, please describe how that process works and what factors public entities consider when making such decisions?

Question 28: What Web content posted by third parties do you consider essential to access in order to engage in civic participation? Is "essential for engaging in civic participation" the appropriate standard for determining whether Web content posted by third parties needs to be made accessible to individuals with disabilities? Please provide as much information as possible, including any supporting material for your views.

Question 29: What factors should the Department consider when framing the obligation for public entities to make accessible the Web content posted by third parties that is essential for engaging in civic participation? Please provide as much information as possible, including any supporting data.

Question 30: Is there other third-party Web content that, while not essential for engaging in civic participation, the public entity controls and should not be included within such an exception? How would the Department define that control? How would the Department measure and evaluate that control? Why, in your view, should that third-party Web content be excluded from any such exception? Please provide as much information as possible, including any supporting data.

Question 31: If the Department adopts an exception along the lines currently under consideration, will it prevent constituents with disabilities from accessing important information on public entities' Web sites concerning public entities' services, programs, or activities? Please provide as much information as possible, including any supporting data for your views.

Question 32: Are there other issues that the Department should take into consideration with regard to the exception under consideration?

3. Third-Party Filings in Judicial and Quasi-Judicial Administrative Proceedings

While access to third-party filings in judicial and quasi-judicial administrative proceedings would seemingly fit within the category of information essential to access in order to engage in civic participation, the Department is considering including these types of filings within the exception for third-party content posted on a public entity's Web site. Courts and administrative agencies can receive vast amounts of third-party filings (*i.e.*, filings made by third parties, not by public entities) in these types of proceedings each year. Some public entities have either implemented an automated process for electronic filing of court documents in legal proceedings via their Web sites or are now beginning to require such a process. After these documents are submitted, some public entities make the electronic record of a case or administrative adjudicatory proceeding available on their Web sites. These conventional electronic documents, submitted by third parties, often include lengthy appendices, exhibits, or other similar supplementary materials that may not be accessible. For example, in a court proceeding, a litigant may submit a brief and exhibits in support of the brief. The exhibits can include a variety of materials (*e.g.*, a written contract, a receipt, a handwritten note, a photograph, a map, or a schematic drawing of a building) to provide support for the propositions asserted in the brief. Items, such as maps or schematic drawings, are inherently visual and cannot easily be made accessible or, in some instances, cannot be made completely accessible. Even when submissions are purely textual documents that are created electronically using word processing software, which can be made accessible easily, the submission may not be in compliance with the accessibility standards contemplated by the Department for its proposed rule, WCAG 2.0 Level AA, if the author of the document did not format the document correctly. Because of the sheer volume of documents public entities receive from third parties in these judicial proceedings and quasi-judicial administrative proceedings, the Department is concerned that it would not be practical to make public entities responsible for ensuring that these kinds of filings by third parties are accessible. Moreover, the need for immediate access to these kinds of documents may generally be confined to a small group, such as parties to a particular proceeding.

However, if the Department were to include within the exception from any Web access requirements third-party filings in judicial proceedings or quasi-judicial administrative proceedings, the Department would make clear that individual requests for access to these excepted documents would need to be addressed on a case-by-case basis in order to ensure that individuals with disabilities are able to receive the benefits or services of the public entity's records program through other effective means. Under title II, it is the responsibility of the public entity that is making the electronic record available to the public to also make these documents accessible to individuals with disabilities. In some instances, third parties that create or submit individual documents may also have an independent obligation to make these documents accessible to individuals with disabilities. However, that independent obligation would not extinguish the duty of public entities under such a proposed exception to provide alternative access to third-party documents that are posted on their Web sites to individuals with disabilities that request access to them. As noted earlier, the current ADA regulation states that "[i]n order to be effective, auxiliary aids and services must be provided in accessible formats, *in a timely manner*, and in such a way as to protect the privacy and independence of the individual with a disability." 28 CFR 35.160(b)(2) (emphasis added). Because of the nature of legal proceedings, it is imperative that individuals with disabilities be provided timely access to the documents to which they request access so that they can take part in the legal process in a manner equal to that afforded to others.

The Department seeks public comment on the exception it is considering and has posed several questions.

Question 33: On average, how many third-party submissions in judicial proceedings or quasi-judicial administrative proceedings does a public entity receive each week or each month? How much staff do public entities have available with the expertise to make such documents accessible? How many staff hours would need to be devoted to making such documents accessible? Please provide as much information as possible, including any supporting data. Has the Department made clear that if an exception were to provide that this content would not need to be made accessible on a public entity's Web site, public entities would continue to have obligations under the current title II requirements to make individual documents accessible to an individual with a disability on a case-by-case basis? If not, why not?

Question 34: The Department is also interested in obtaining information about what types of third-party Web content in judicial and quasi-judicial administrative proceedings are posted on public entities' Web sites (e.g., how much of it is text, how much contains images, videos, audio content, or other forms of media)? Please provide as much information as possible, including any supporting data.

Question 35: If the Department adopts an exception along the lines currently under consideration, will it prevent citizens with disabilities from accessing important information concerning public entities' services, programs, or activities on public entities' Web sites? Please provide as much information as possible, including any supporting data for your views.

Question 36: Are there other issues or other factors that the Department should take into consideration with regard to this proposal regarding third-party filings in judicial and quasi-judicial administrative proceedings?

4. Third-Party Social Media Platforms

Public entities are increasingly using third-party platforms, including social media platforms, to host forums for public discourse or to provide information about their services, programs, and activities in lieu of or in addition to hosting such forums and information on their own Web sites. At this time, the Department is considering deferring, in any proposed rule for Web access for public entities, proposing a specific technical accessibility standard that would apply to public entities' use of third-party social media platforms until the Department issues a rulemaking for public accommodations addressing Web site accessibility under title III. For the purposes of this possible deferral, third-party social media platforms would refer to Web sites of third parties whose primary purpose is to enable users to create and share content in order to participate in social networking (*i.e.*, the creation and maintenance of personal and business relationships online through Web sites such as, for example, Facebook, YouTube, Twitter, and LinkedIn). The only social media platforms that the Department is aware of are public accommodations covered by title III, thus, the Department believes it may be appropriate to defer addressing social media platforms for this title II rulemaking until it issues a proposed title III Web accessibility regulation.

Although the Department is considering deferring application of a technical standard to third-party social media Web sites that public entities use to provide services, programs, or activities, public entities would continue to have obligations under title II of the ADA to provide persons with disabilities access to these online services, programs, or activities. Under title II, a public entity must ensure that "[n]o qualified individual with a disability shall, on the basis of disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any public entity," and must refrain from using methods of administration that would subject qualified individuals with disabilities to discrimination on the basis of disability. *See* 35 CFR 35.130(a) and 35.130(b)(3). Thus, when using a third-party social media Web site to implement its services, programs, or activities, a public entity is required to ensure access to that content for individuals with disabilities through other means. For example, if a public entity publishes information about an upcoming event on a third-party social media Web site, it must ensure that the same information about the event is also available to individuals with disabilities elsewhere, such as on the public entity's accessible Web site. Likewise, if a public entity solicits public feedback on an issue via a social media platform, the public entity must provide an alternative way to invite and receive feedback from person with disabilities on that topic.

Question 37: Are there any social media platforms that are covered by title II of the ADA that the Department should be aware of? Please provide as much information as possible in your response.

Question 38: Please provide any other information or issues that the Department should consider with regard to a proposal to defer applying a technical standard to public entities' use of social media Web sites.

D. Password-Protected Web Content of Public Educational Institutions

Public educational institutions (*i.e.*, public elementary and secondary schools and public postsecondary institutions), like many other public institutions, use their Web sites to provide a variety of services, programs, and activities to members of the public. Many of the services, programs, and activities on these Web sites are available to anyone—access simply requires an Internet connection and the relevant Web site address, which can be obtained using a search engine. The content on these public Web sites can include such general information as the academic calendar, enrollment process, admission requirements, school lunch menus, school policies and procedures, and contact information of school, college, or university administrators. Under the Web access rule under consideration by the Department, all such services, programs, or activities available to the public on the Web sites of public educational institutions would be required to comply with the technical standards the Department adopts.

In addition to the information available to the general public on the Web sites of public educational institutions, however, the Web sites of many schools, colleges, and universities also make certain services, programs, and activities available to a discrete and targeted audience of individuals (*e.g.*, students taking particular classes or courses). This information is often provided using a Learning Management System (LMS) or similar platform that can provide secure online access and allow the exchange of educational and administrative information in real time. LMSs allow public educational institutions and institutions' faculty and staff to exchange with students specific information about the course, class, or student's progress. For example, faculty and staff can create and collect assignments, post grades, provide real-time feedback, and share subject-specific media, documents, and other resources to supplement and enrich the curriculum. Parents can track their children's attendance, assignments, individualized education programs (IEPs), grades, and upcoming class events. To access the information available on these platforms, students—and parents in certain contexts—generally must obtain password or login credentials from the educational institution.

Under the ADA, public entities are prohibited from providing any aid, benefit, or service directly, or through contracting, that discriminates against individuals with disabilities. *See* 28 CFR 35.130(b). The Department is therefore considering proposing a provision that would require that the LMS or other educational platforms that public elementary and secondary schools, colleges, and universities use be readily accessible in accordance with a Web access rule. However, because access to password-protected class or course Web content is limited to a discrete population, which may not always include a person with a disability, the Department is also considering a provision that would not require the content available on these password-protected class or course pages to be made accessible unless and until a student with a disability enrolls in such a class or course. For example, a blind university student may not have enrolled in a psychology course, or a deaf high school student may not have enrolled in a particular ninth grade world history class. As such, the Department is considering a proposal to except content available on password-protected Web sites for specific classes or courses unless and until a student enrolls in that particular class or course and, because of a disability, that student would be unable to access the content posted on the password-protected Web site for that class or course. However, under the proposal under consideration by the Department, once a student with a disability has enrolled in a particular class or course, the content available on the password-protected Web site for the specific class or course would need to be made accessible in a timely manner.

The Department is also concerned about the rights of parents with disabilities, particularly in the public elementary and secondary school context. Because parents of students in these contexts have greater rights, roles, and responsibilities with regard to their children and their children's education than may be present in the postsecondary education setting, and because these parents interact with such schools much more and in much greater depth and detail, the Department currently is considering expressly including parents with disabilities in any proposed exception and subsequent limitation for password-protected Web content. (The Department notes that the term "parent" in any proposed regulation would be intended to include, at present, natural, adoptive, step-, or foster parents, legal guardians, or other individuals recognized under Federal or State law as having parental rights.) Parents use educational platforms to access progress reports and grades, track homework and long-term project assignments, interact regularly with their children's teachers and administrators, and follow IEP plans and progress. Thus, under the proposal currently under consideration by the Department, once a student is enrolled in a particular class or course and that student has a parent with a disability, the content available on the password-protected Web site would also be required to be made accessible in a timely manner.

Public educational institutions are required to make the appropriate modifications and provide the necessary auxiliary aids and services to students with disabilities. It is the public institution, not the student, that is responsible for ensuring that the required modifications are made and necessary auxiliary aids and services are provided once it is on notice of a student's need. Such institutions, therefore, must think prospectively regarding the access needs of its students with disabilities, including those who would be unable to access course content on an inaccessible Web site. This also means that institutions should not expect or require that a student with a disability, whom the institution knows is unable to access content on an inaccessible Web site, first attempt to access the information and be unable to do so before the institution's obligation to make the content accessible arises.

The Department believes that considering a proposal for public educational institutions along these lines would provide a balanced approach, ensuring access to students with disabilities enrolled in a public educational institution while recognizing that there are large amounts of class or course content that may never need to be accessed by individuals with disabilities because they have not enrolled in a particular class or course.

The exception under consideration by the Department is not intended to apply to password-protected content for classes or courses, that are made available to the general public without enrolling at a particular educational institution and that generally only require perfunctory, if any, registration or payment to participate in the classes or courses, including those offered exclusively online (*e.g.*, many Massive Open Online Courses (MOOCs)). Access to the content on these password-protected Web sites is not confined to a discrete student population within an educational institution, but is instead widely available to the general public—sometimes without limits as to enrollment. Accordingly, any individual, including one with a disability, may enroll or participate at almost any time. Under these circumstances, it is the Department's position that the public entity should make such class or course content accessible from the outset of the class or course regardless of whether a student with a disability is known to be participating in the class or course because a student with a disability, like any other student, may enroll at any time. The Department seeks public comment on a number of issues implicated by the proposed exception that the Department is considering for public educational institutions' password-protected Web content.

Question 39: Does the Department's exception, as contemplated, take into account how public educational institutions use password-protected Web content? What kinds of tasks are students with disabilities or parents with disabilities performing on public educational institutions' Web sites?

Question 40: How do public educational institutions communicate general information to their student bodies and how do they communicate class- or course-specific information to their students via Web sites?

Question 41: On average, how much and what type of content do password-protected course Web sites contain? How much time does it take a public entity to make the content on a password-protected course Web site accessible? Once a public educational institution is on notice that a student is enrolled in a class or course, how much time should a public educational institution be given to make the content on a password-protected course Web site accessible? How much delay in accessing course content can a student reasonably overcome in order to have an equal opportunity to succeed in a course?

Question 42: Do public elementary or secondary schools combine and make available content for all students in a particular grade or particular classes (e.g., all ninth graders in a school or all secondary students taking chemistry in the same semester) using a single password-protected Web site?

Question 43: Is the Department's proposed terminology to explain who it considers to be a parent in the educational context clear? If not, why not? If alternate terminology is appropriate, please provide that terminology and data to support your position that an alternate term should be used.

Question 44: Should the Department require that password-protected Web content be accessible to parents with disabilities who have a postsecondary student enrolled in a particular class or course?

Question 45: How and when do public postsecondary educational institutions receive notice that a student who, because of a disability, would be unable to access content on an inaccessible Web site is newly enrolled in a school, class, or course?

Question 46: When are public elementary and secondary students generally assigned or enrolled in classes or courses? For all but new students to a public elementary or secondary school, does such enrollment generally occur in the previous semester? If not, when do such enrollments and assignments generally occur?

Question 47: Are there other factors the Department should consider with regard to password-protected Web content of public educational institutions? Please provide as much detail as possible in your response.

IV. Conforming Alternate Versions

The Department is considering allowing the use of conforming alternate versions to provide access to Web content for individuals with disabilities in two limited circumstances that are discussed below. In order to comply with WCAG 2.0, Web content must satisfy one of the defined levels of conformance (*i.e.*, Level A, Level AA, or Level AAA) or a separate accessible Web page must be provided that satisfies one of the defined levels of conformance as an alternative to the inaccessible Web page. These separate accessible Web pages are referred to as "conforming alternate versions" in WCAG 2.0. WCAG 2.0 describes "conforming alternate version" as a separate Web page that is accessible, up-to-date, contains the same information and functionality as the inaccessible Web page, and, therefore, can provide individuals with disabilities equivalent access to the information and functionality provided to individuals without disabilities. *See* W3C®, *Understanding WCAG 2.0: Understanding Conforming Alternate Versions* (Dec. 2012), available at *http://www.w3.org/TR/UNDERSTANDING-WCAG20/conformance.html#uc-conforming-alt-versions-head* (last visited Apr. 13, 2016). The W3C® explains that providing a conforming alternate version of a Web page is intended to be a "fallback option for conformance to WCAG and the preferred method of conformance is to make all content directly accessible." *Id.*

The Department is concerned that WCAG 2.0 will be interpreted to permit the development of two separate Web sites—one for individuals with disabilities and another for individuals without disabilities—even when doing so is unnecessary. The Department is also concerned that the creation of separate Web sites for individuals with disabilities may result in unequal access to information and functionality. However, as the W3C® explains, certain limited circumstances may warrant the use of conforming alternate versions of Web pages. For example, a conforming alternate Web page may be necessary when a new emerging technology is used on a Web page, but the technology is not yet accessibility supported (*i.e.*, the technology is not yet able to be made accessible) or when a Web site owner is legally prohibited from modifying the Web content. *Id.* The Department is considering permitting the use of conforming alternate versions of Web page and Web content, as defined by 2008 WCAG 2.0, to comply with Web accessibility requirements only under the following two circumstances:

(1) when it is not possible to make Web content directly accessible due to technical or legal limitations; or

(2) when used to provide access to conventional electronic documents.

Under this approach, it would not be permissible for public entities to provide conforming alternate versions in cases where making the main Web site accessible would result in an undue financial and administrative burden. As discussed below, in section V. "Compliance Limitations and Other Duties," public entities are required to make their main Web sites accessible up to the point that full compliance with the proposed technical standard is an undue financial and administrative burden. The Department would not, at that point, also require the public entity to expend significant additional resources to develop a separate accessible and up-to-date Web site that contains the same information and functionality as the inaccessible Web content.

A. Technical or Legal Limitations

The Department believes persons with disabilities must be provided access to the same Web content that is available to persons without disabilities unless providing direct access to that Web content to persons with disabilities is not possible due to technical or legal limitations. The Department's proposed approach under the ADA would be slightly different than WCAG 2.0 because under WCAG 2.0 public entities, despite the W3C® guidance, can always choose to provide a conforming alternate version of a Web page to conform to WCAG 2.0 rather than providing Web content on the Web page that is directly accessible, even when doing so is unnecessary. Thus, the Department's proposal under consideration would permit the use of conforming alternate versions of Web pages and Web content to comply with Web accessibility requirements only where it is not possible to make Web pages and Web content directly accessible due to technical limitations (*e.g.*, technology is not yet accessibility supported) or legal limitations (*e.g.*, Web content is protected by copyright). The responsibility for demonstrating a technical or legal limitation would rest with the covered entity.

For many individuals with disabilities, having direct access to a main Web page that is accessible is likely to provide the best user experience; however, the Department is aware that for some individuals with disabilities a Web page specifically tailored to accommodate their specific disability may provide a better experience. Nonetheless, requiring all individuals with disabilities who could have a better experience using the main Web page to use a separate or segregated Web page created to accommodate certain disabilities is concerning and inconsistent with the ADA's integration principles. 28 CFR 35.130(b)(2). Still, the Department's proposal under consideration would not prohibit public entities from providing alternate versions of Web pages in addition to its accessible main Web page to provide users with certain types of disabilities a better experience.

B. Providing Access to Conventional Electronic Documents

With regard to conventional electronic documents (*e.g.*, PDFs, word processing documents, or other similar electronic documents) the Department is considering proposing that where a public entity provides more than one version of a single document, only one version of the document would need to be accessible and, thus, that accessible version would be the conforming alternate version for the inaccessible version. For example, if a public entity provides both PDF and Microsoft Word versions of a single document, either the PDF or the Microsoft Word document would need to comply with WCAG 2.0, but both would not need to comply. Therefore, in this example, a public entity would not be required to remediate an inaccessible PDF where a WCAG 2.0-compliant Microsoft Word version is also provided on the public entity's Web site (*i.e.*, the Microsoft Word document acts as a conforming alternate version providing accessible information to individuals with disabilities).

The Department is concerned about the work it may take to make multiple versions of the same conventional electronic documents accessible, particularly when public entities are already providing persons with disabilities access to the information contained in those documents. Additionally, making more than one format accessible may not improve the access to or experience of the document's content for individuals with disabilities. In the context of conventional electronic documents, the Department does not believe the same risks of separate and unequal access are necessarily present that may occur when using conforming alternate versions for other types of Web content and Web pages, which can lead to the unnecessary development of separate Web sites or unequal services for individuals with disabilities. It seems to the Department that conventional electronic documents are updated less frequently than Web pages and are often replaced in their entirety by new versions of the documents. In contrast, it appears that other types of Web content and Web pages are often updated piecemeal, increasing the possibility that the content on the alternate accessible Web page may not be updated concurrently and therefore would not be the same as that provided on the primary Web page. Because conventional electronic documents do not appear to be updated as frequently as Web pages and generally do not change unless they are replaced in their entirety by another version of the document, the risk that individuals with disabilities would not get the same content or services as those without disabilities seems relatively low. The approach with regard to conforming alternate versions the Department is considering is consistent with the U.S. Access Board's approach in its Notice of Proposed Rulemaking on section 508. 80 FR 10880 (Feb. 27, 2015).

Question 48: Has the Department made clear the two circumstances under which conforming alternate versions of Web pages or Web content would be permissible? Please provide as much detail as possible in your response.

Question 49: Are there other instances where the Department should consider permitting the use of conforming alternate versions of Web pages or Web content? Please provide as much detail as possible in your response.

Question 50: Are there any issues or considerations the Department should take into account regarding its proposal to permit the use of conforming alternate versions of Web pages or Web content only where it is not possible to make Web pages and Web content directly accessible to persons with disabilities due to technical or legal limitations? Are there any additional issues or information regarding conforming alternate versions of a Web page or Web content that the Department should consider? Please provide as much detail as possible in your response.

Question 51: Should the Department consider permitting the use of conforming alternate versions to provide access to conventional electronic documents when multiple versions of the document exist? If so, why? Are there considerations or concerns regarding whether allowing conforming alternate versions in these specific instances would subject individuals with disabilities to different or inferior services? Please provide as much detail as possible in your response.

V. Compliance Limitations and Other Duties

The Department is considering a proposal that would provide that in meeting any access requirements in a Web accessibility rule, a public entity would not be required to take any action that would result in a fundamental alteration or undue financial and administrative burden. The limitations under consideration would be consistent with the compliance limitations currently provided in the title II regulation in 28 CFR 35.130(b)(7) (reasonable modifications in policies, practices, or procedures), 35.150(a)(3) (program accessibility), and 35.164 (effective communication) and, thus, are familiar to public entities. The regulatory text under consideration may look like the following:

> (a) Where a public entity can demonstrate that full compliance with Web accessibility requirements would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, compliance with Web accessibility requirements is required to the extent that it does not result in a fundamental alteration or undue financial and administrative burdens. In those circumstances where personnel of the public entity believe that the proposed action would fundamentally alter the service, program, or activity or would result in undue financial and administrative burdens, a public entity has the burden of proving that compliance with Web accessibility requirements would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of a public entity or his or her designee after considering all resources available for use in the funding and operation of the service, program, or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, a public entity shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with disabilities receive the benefits or services provided by the public entity to the maximum extent possible.
>
> (b) A public entity that has complied with (a) above is not required to make any further modifications to its Web site to accommodate an individual with a disability who cannot access the information, service, program, or activity on the public entity's Web site. However, the public entity must utilize an alternative method of providing the individual with a disability equal access to that information, service, program, or activity unless the public entity can demonstrate that alternative methods of access would result in a fundamental alteration in the nature of a service, program, or activity or undue financial and administrative burdens.

Generally, the Department believes that it would not be a fundamental alteration of a public entity's online services, programs or activities to modify a Web site or Web content in order to make it accessible and ensure access for individuals with disabilities to such services, programs or activities. Moreover, like the limitations in the title II regulation referenced above, the Department does not believe that such a proposal would relieve a public entity of all obligations to individuals with disabilities. Although a public entity would not be required to take actions that would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, it nevertheless would be required to comply with the Web accessibility requirements under consideration *to the extent* they do not result in a fundamental alteration or undue financial and administrative burdens. For instance, a public entity might determine that full compliance with WCAG 2.0 Level AA would result in a fundamental alteration or undue financial and administrative burdens. However, this same public entity would then be required to determine whether it can bring its Web content into partial compliance with Level AA. To the extent it can, the public entity would be required to do so.

The Department believes that there are many steps a public entity could take to comply with WCAG 2.0 Level AA that would not result in undue financial and administrative burdens and that most entities that would assert a claim that full compliance would result in undue financial and administrative burdens would be able to attain compliance with at least some of the requirements of WCAG 2.0 Level AA. For instance, a public entity may be able to edit its Web content so that all non-text content (*e.g.*, images) has a text alternative that contains an equivalent written description enabling an individual's screen reader to interpret the image or non-text to allow the individual to access the information. A public entity may also be able to provide skip navigation links so users with screen readers can skip past the navigation headers to the main information on the Web page. Most public entities also could easily ensure that each Web page has a title that describes the topic or purpose of that page, making it easier for individuals navigating the Web content with a screen reader to determine if a particular Web page has the content they are looking for without having the screen reader read through all the content on the page. These and other requirements of WCAG 2.0 Level AA are not, in the Department's view, likely to be difficult or unduly burdensome for a public entity.

In determining whether an action constitutes undue financial and administrative burdens, all of a public entity's resources available for use in the funding and operation of the service, program, or activity would need to be considered. The burden of proving that compliance with Web accessibility requirements under consideration would fundamentally alter the nature of a service, program, or activity or would result in undue financial and administrative burdens rests with the public entity. As the title II regulation has provided since the Department's adoption in 1991, the decision that compliance would result in a fundamental alteration or impose undue burdens must be made by the head of the public entity or the head's designee and must be memorialized with a written statement of the reasons for reaching that conclusion. *See* 28 CFR 35.150(a)(3) and *The Americans with Disabilities Act Title II Technical Assistance Manual: Covering State and Local Government Programs and Services* (Nov. 1993), available at *http://www.ada.gov/taman2.html.* The Department recognizes that some public entities may have difficulty identifying the official responsible for this determination, given the variety of organizational structures among public entities and their components. 28 CFR part 35, app. B, 695 (2015). The proposal the Department is considering would make it clear that the determination must be made by a high level official, no lower than a department head, having budgetary authority and responsibility for making spending decisions, as is true under the existing title II regulation.

As contemplated by the Department in paragraph (b) above, once a public entity has complied with WCAG 2.0 Level AA, it would not be required to make further modifications to its Web page or Web content to accommodate an individual who is still unable to access the Web page or Web content due to a disability. While the Department realizes that the Web accessibility requirements under consideration may not meet the needs of and provide access to every individual with a disability, it believes that setting a consistent and enforceable Web accessibility standard that meets the needs of a majority of individuals with disabilities would provide greater predictability for public entities, as well as greater assurance of accessibility for individuals with disabilities.

As noted above, full compliance with the Web accessibility requirements under consideration means a public entity would not be required to make any further modifications to its Web page or Web content if an individual with a disability is still unable to access information on the public entity's accessible Web page. However, public entities would still have an obligation to provide the individual with a disability an alternative method of access to that information, service, program, or activity unless the public entity could demonstrate that alternative methods of access would result in a fundamental alteration or in undue financial and administrative burdens. Thus, full compliance with the Web accessibility standards would not mean necessarily full compliance with all of a public entity's obligations under the ADA. In these circumstances, a public entity would still need to take other steps to ensure that an individual with a disability is able to gain access through other effective means, although no further changes to its Web site would be required. This could be accomplished in a variety of ways, including ensuring that the information or services could be accessed by telephone or in person.

The Department would emphasize in a proposed rule that the public entity must make the determination on a case-by-case basis of how best to accommodate those individuals who cannot access the information or services through the public entity's fully compliant Web site. The Department also intends to convey that a public entity should refer to the existing title II regulation at 28 CFR 35.160 (effective communication) to determine its obligations to provide individuals with communication disabilities with the appropriate auxiliary aids and services necessary to afford them an equal opportunity to participate in, and enjoy the benefits of, the public entity's service, program, or activity. For individuals with other disabilities who are unable to access all the information or services provided through a public entity's fully compliant Web site, a public entity should refer to 28 CFR 35.130(b)(7) (reasonable modifications) to determine what reasonable modifications in policies, practices, or procedures are necessary to avoid discrimination on the basis of disability. Under any proposal it advances, the Department will strongly recommend that the public entity provide notice to the public on how an individual who cannot use the Web site because of a disability can request other means of effective communication or reasonable modifications in order to access the information or to participate in the public entity's services, programs, or activities that are being provided on the public entity's Web site. For example, a public entity could provide an email address, link, Web page, or other means of contacting the public entity to address issues that individuals with disabilities may encounter when accessing Web content. The Department seeks additional information with regard to compliance limitations and other duties. Please refer to Question 100 in section VI.C.8 "Compliance Limitations."

VI. Additional Issues for Public Comment

A. Measuring Compliance

As noted in the 2010 ANPRM, the Department believes that while there is a need to adopt specific standards for public entities to use in order to ensure that their Web content is accessible to individuals with disabilities, the Department must move forward with care, weighing the interests of all stakeholders, so that as accessibility for individuals with disabilities is improved, innovation in the use of the Web by covered entities is not hampered. *See* 75 FR 43460, 43464 (July 26, 2010). The Department appreciates that the dynamic nature of Web sites presents unique compliance challenges. Therefore, the Department is also seeking public comment on issues concerning how best to measure compliance with the Web accessibility requirements it is considering proposing.

The Department is concerned that the type of ADA compliance measures it currently uses, such as the one used to assess compliance with the ADA Standards, may not be practical in the Web context. The ADA requires the facilities of public entities to be designed and constructed in such a manner that the facilities are readily accessible to and usable by individuals with disabilities. 42 U.S.C. 12146. Public entities must ensure that newly designed and constructed State and local government facilities are in full compliance with the scoping and technical specifications in the ADA Standards unless it is structurally impracticable to do so. 28 CFR 35.151(a). When making an alteration to a facility that affects or could affect usability, public entities are required to make those alterations accessible to the maximum extent feasible. 28 CFR 35.151(b).

Because of the dynamic and interconnected nature of Web sites and the large amount of and wide variety of Web content contained on those sites, the Department is concerned that a compliance measure similar to the one used for buildings—where State and local government facilities are to be 100-percent compliant at all times with all of the applicable provisions of the ADA Standards, subject to a few applicable compliance limitations—may not work well in the Web context. Accordingly, the Department is considering what should be the appropriate measure for determining compliance with WCAG 2.0 Level AA.

Question 52: The Department is seeking public comment on how compliance with WCAG 2.0 Level AA should be assessed or measured, particularly for minor or temporary noncompliance. Should the Department consider adopting percentages of Web content that need to be accessible or other similar means of measuring compliance? Is there a minimum threshold that is an acceptable level of noncompliance for purposes of complaint filing or enforcement action? Are there circumstances where Web accessibility errors may not be significant barriers to accessing the information or functions of the Web site? Please provide as much detail as possible in your response.

B. Mobile Applications

The Department is considering whether it should address the accessibility of mobile applications (mobile apps) and, if so, what standard it should consider adopting to address the accessibility of these mobile apps. As mentioned in section II.A "The Meaning of 'Web Content'" above, although the Department's proposal under consideration would generally not cover software, the Department is soliciting public comment on whether it should address the accessibility of mobile apps because public entities seem to be turning to mobile apps to provide their services, programs, and activities.

A mobile app is a software application designed to run on smart phones, tablets, or other mobile devices. Today, public entities are increasingly using mobile apps to provide services more effectively and to reach citizens in new ways. For example, using a city's mobile app, residents are able to submit to the city nonemergency service requests, such as cleaning graffiti or repairing a streetlight outage, and track the status of these requests. Public entities' apps take advantage of common features of mobile devices, such as Global Positioning System (GPS) and camera functions, so citizens can provide public entities with a precise description and location of street-based issues, such as potholes or physical barriers created by illegal dumping or parking. Some public transit authorities have transit apps that use a mobile device's GPS function to provide bus riders with the location of nearby bus stops and real-time arrival and departure times. In addition, public entities are not only using mobile apps as a new way to provide civil services, but are also using them to promote tourism, culture, and community initiatives.

One option for a standard would be to apply WCAG 2.0 Level AA to mobile apps of public entities as is being proposed by the Access Board in its update to the section 508 standards. *See* 80 FR 10880 (Feb. 27, 2015). WCAG 2.0 is designed to apply to Web content available on standard Web sites designed for desktop, laptop, or notebook computers, as well as Web content available on mobile Web sites designed for smart phones, tablets, or other mobile devices. *See W3C WAI Addresses Mobile Accessibility,* WAI Education and Outreach Working Group (Sept. 26, 2013), available at *http://www.w3.org/WAI/mobile/#covered* (last visited Apr. 13, 2016). WCAG 2.0 is not intended to apply to software, including mobile apps; however, as noted by the Access Board in its proposed revision to the section 508 standards, the W3C® developed WCAG 2.0 to be technology neutral and there is some support suggested for its application to other technologies, including mobile apps. *See* 80 FR 10880, 10895 (Feb. 27, 2015). In fact, the WCAG2ICT Task Force developed a W3C® Working Group Note that addressed the issue of applying WCAG 2.0's Success Criteria to offline content and software. *See Guidance on Applying WCAG 2.0 to Non-Web Information and Communications Technologies (WCAG2ICT),* WCAG2ICT Task Force, (Sept. 5, 2013), available at *http://www.w3.org/TR/wcag2ict/* (last visited Apr. 13, 2016). The WCAG2ICT Task Force found that the majority of WCAG 2.0's Success Criteria could be applied to software with minimal or no changes. *Id.* However, the WCAG2ICT Task Force acknowledged that the W3C® Working Group Note is a work in progress and does not imply endorsement by the W3C®. *Id.* (set forth under section titled "Status of this Document," available at *http://www.w3.org/TR/wcag2ict/#sotd*) (last visited Apr. 13, 2016).

Additionally, the Mobile A11Y Task Force, another task force of the WAI, developed a W3C® First Public Working Draft that addressed the issue of applying WCAG 2.0 and other W3C® guidelines to mobile apps. *See Mobile Accessibility: How WCAG 2.0 and Other W3C/WAI Guidelines Apply to Mobile,* Mobile A11Y Task Force, (Feb. 26, 2015), available at *http://www.w3.org/TR/2015/WD-mobile-accessibility-mapping-20150226/* (last visited Apr. 13, 2016). The Mobile A11Y Task Force found that although the majority of the WCAG 2.0 Success Criteria can be applied to mobile apps, WCAG 2.0 did not provide testable success criteria for some of the mobile-specific accessibility issues because mobile devices present a mix of accessibility issues that are different from typical desktop and notebook computers. The Mobile A11Y Task Force recommended supplementing WCAG 2.0 with other W3C® guidelines such as the User Agent Accessibility Guidelines (UAAG) 2.0, available at *http://www.w3.org/TR/UAAG20/* (last visited Apr. 13, 2016), and the Authoring Tool Accessibility Guidelines (ATAG) 2.0, available at *http://www.w3.org/TR/ATAG20/* (last visited Apr. 13, 2016). Similar to the WCAG2ICT Task Force above, the Mobile A11Y Task Force also acknowledged that the W3C® First Public Working Draft is a work in progress and does not imply endorsement by the W3C®. *Id.* (set forth under section titled *Status of this Document,* available at *http://www.w3.org/TR/2015/WD-mobile-accessibility-mapping-20150226/#sotd*) (last visited Apr. 13, 2016).

A second possible option for an accessibility standard to apply to mobile apps would be to apply the UAAG, which is also published by the W3C®. The W3C® has published a draft UAAG 2.0, which addresses the accessibility of Web browser software, mobile apps, and other software. *See User Agent Accessibility Guidelines (UAAG) 2.0, W3C® Working Group Note,* (Dec. 15, 2015), available at *http://www.w3.org/TR/UAAG20/* (last visited Apr. 13, 2016). UAAG 2.0 is currently under development, but the guidelines will likely be finalized before the Department publishes a final rule. Once UAAG 2.0 is finalized, the Department could consider the guidelines for adoption as an accessibility standard for mobile apps. Unlike WCAG, however, UAAG does not appear to have been widely accepted, but this may be attributable to the fact that the most recent final version of the guidelines, UAAG 1.0, which was published in 2002, may not be as useful in making more current software accessible.

A third possible option for an accessibility standard to apply to mobile apps would be to apply the ATAG, which is also published by the W3C®. The W3C® published the final version of ATAG 2.0 on September 24, 2015. *See Authoring Tool Accessibility Guidelines (ATAG) 2.0,* (Sep. 24, 2015), available at *http://www.w3.org/TR/ATAG20/* (last visited Apr. 13, 2016). ATAG 2.0 provides guidelines that address the accessibility of Web content authoring tools (*i.e.,* the accessibility of specialized software that Web developers and designers use to produce Web content). Like the UAAG, ATAG does not appear to have been as widely accepted as WCAG.

A fourth possible option for an accessibility standard to apply to mobile apps would be the Human Factors and Ergonomics Society's ANSI/HFES 200. *See ANSI/HFES 200 Human Factors Engineering of Software User Interfaces,* Human Factors and Ergonomics Society (2008), available at *http://www.hfes.org/Publications/ProductDetail.aspx?ProductID=76* (last visited Apr. 13, 2016). ANSI/HFES 200 provides requirements to design user interfaces of software that are more usable, accessible, and consistent. However, like the UAAG and ATAG, ANSI/HFES 200 does not appear to be as widely accepted as WCAG.

Question 53: Should the Department consider adopting accessibility requirements for mobile software applications to ensure that services, programs, and activities offered by public entities via mobile apps are accessible? Please provide any information or issues the Department should consider regarding accessibility requirements for mobile apps provided by public entities.

Question 54: The Department is seeking public comment regarding the use of WCAG 2.0, UAAG 2.0, ATAG 2.0, or ANSI/HFES 200 as accessibility requirements for mobile apps. Are there any issues the Department should consider in applying WCAG 2.0, UAAG 2.0, ATAG 2.0, or ANSI/HFES 200 as accessibility requirements for mobile apps? Is there a difference in compliance burdens and costs between the standards? Please provide as much detail as possible in your response.

Question 55: Are there any other accessibility standards or effective and feasible alternatives to making the mobile apps of public entities accessible that the Department should consider? If so, please provide as much detail as possible about these alternatives, including information regarding their costs and effectiveness, in your response.

C. Benefits and Costs of Web Access Regulations

The Department anticipates that any proposed or final rule that the Department issues regarding the accessibility of Web information and services of public entities would likely have an economically significant impact. A proposed regulatory action is deemed to be "economically significant" under section 3(f)(1) of Executive Order 12866 if it has an annual effect on the economy of $100 million or more or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Under Executive Order 12866, regulatory actions that are deemed to be economically significant must include a regulatory analysis—a report that documents an agency's analysis of the benefits and costs of the regulatory action. A benefit-cost analysis must include both qualitative and quantitative measurements of the benefits and costs of the proposed rule as well as a discussion of each potentially effective and reasonably feasible alternative.

Because this is a SANPRM, the Department is not required to conduct a benefit-cost analysis required for other more formal types of agency regulatory actions (*e.g.,* notices of proposed rulemaking or final rules). The Department, however, is soliciting input from the public in this SANPRM to gather information and data that will help the Department prepare a regulatory analysis at the next stage of the rulemaking process.

In its 2010 ANPRM, the Department requested public comment on the benefits and costs of a proposed rule regarding the accessibility of Web information and services of public entities and public accommodations. The Department received very little specific information or data on the anticipated costs or benefits of such a rule in response to the 2010 ANPRM. The Department therefore seeks additional information that will enable it to more precisely quantify and monetize the economic impact of a rule requiring public entity Web sites to be accessible. The Department asks that any responses to these requests for public comment on the potential benefits and costs of this rule include as much detail as possible and be supported by specific data, information, or research where applicable.

1. Web Accessibility Benefits

Millions of individuals in the United States have disabilities that could affect their use of the Web. Individuals who have vision disabilities often confront significant barriers to Web access because, among other limitations, many Web sites provide information visually without features that enable screen readers or other assistive technology to retrieve the information on the Web site so it can be presented in an audio or tactile form. Individuals with hearing disabilities face accessibility challenges when, for example, audio content is not presented in a visual form such as captions or transcripts. Individuals with cognitive disabilities can experience difficulties in accessing Web content when information cannot be presented in a text or audio form, distractions cannot be reduced, or time limitations cannot be extended. Individuals with disabilities that affect manual dexterity might, for example, need Web sites to allow input from specialized hardware and software.

Lack of accessibility prevents individuals with disabilities from taking full advantage of Web-implemented governmental programs, services, and activities, which are becoming increasingly common and important. The Department believes that Web accessibility will provide significant benefits to individuals with disabilities, such as the ability to access additional information about government services, programs, or activities, and to access this information more quickly, easily, and independently. The Department has obtained limited information, however, that would enable it to quantify and monetize these and other benefits of Web accessibility for individuals with disabilities, particularly those with disabilities other than visual impairments. For example, it is unclear how much time an individual with a hearing disability would save by using an accessible Web site to access information about city council hearings instead of attempting to obtain this information on an inaccessible Web site or by using a video relay service. Similarly, it is unclear what monetary value should be associated with this time savings, whether time savings is the most appropriate way to measure the monetary value of Web accessibility, or if not, how a monetary value could be assigned to the many benefits Web accessibility provides to individuals with disabilities.

As described above, because the Department expects that any proposed or final rule it issues regarding the accessibility of Web information and services of public entities is likely to have an economically significant impact, the Department will be required to prepare a benefit-cost analysis that assesses the qualitative and quantitative benefits of the proposed rule. The Department therefore seeks additional information about the benefits of Web accessibility for various disability groups that will assist the Department in preparing this required benefit-cost analysis. Please include as much information as possible to support each of your responses, including specific data or research where possible.

a. Benefits for People With Disabilities

Question 56: How should the monetary value of the benefits of Web accessibility to persons with disabilities be measured? What methodology should the Department use to calculate the monetary value of these benefits? Please provide any available data or research regarding the benefits of Web accessibility and the monetary value of these benefits.

Question 57: Are there particular benefits of Web accessibility for persons with disabilities that are difficult to quantify (e.g., increased independence, autonomy, flexibility, access to information, civic engagement, educational attainment, or employment opportunities)? Please describe these benefits and provide any information or data that could assist the Department in estimating their monetary value.

Question 58: People with vision disabilities: What data should the Department use for estimating the number of people with vision disabilities who would benefit from a Web access regulation (e.g., the Survey of Income and Program Participation, available at http://www.census.gov/prod/2012pubs/p70-131.pdf, or the American Community Survey, available at http://www.disabilitystatistics.org/reports/acs.cfm?statistic=1)? How does Web accessibility benefit people with vision disabilities? Please provide any information that can assist the Department in quantifying these benefits.

Question 59: People who are deaf or hard of hearing: What data should the Department use for estimating the number of people with hearing disabilities who would benefit from a Web access regulation (e.g., the Survey of Income and Program Participation, available at http://www.census.gov/prod/2012pubs/p70-131.pdf, or the American Community Survey, available at http://www.disabilitystatistics.org/reports/acs.cfm?statistic=1)? How does Web accessibility benefit people who are deaf or hard of hearing? Is there any data or studies available that examine how often people seek and use sound when visiting public entity (or other) Web sites? Please provide any information that can assist the Department in quantifying these benefits.

Question 60: People who have disabilities that impair manual dexterity: What data should the Department use for estimating the number of people with manual dexterity disabilities who would benefit from a Web access regulation (e.g., the Survey of Income and Program Participation, available at http://www.census.gov/prod/2012pubs/p70-131.pdf, or the American Community Survey, available at http://www.disabilitystatistics.org/reports/acs.cfm?statistic=1)? How does Web accessibility benefit people who have disabilities that impair manual dexterity? Please provide any information that can assist the Department in quantifying these benefits.

Question 61: People with cognitive disabilities: What data should the Department use for estimating the number of people with cognitive disabilities who would benefit from a Web access regulation (e.g., the Survey of Income and Program Participation, available at http://www.census.gov/prod/2012pubs/p70-131.pdf, or the American Community Survey, available at http://www.disabilitystatistics.org/reports/acs.cfm?statistic=1)? How does Web accessibility benefit people with cognitive disabilities? Clinical diagnoses of cognitive disabilities can sometimes include a wide spectrum of disabilities including learning disabilities, developmental disabilities, neurological disabilities, and intellectual disabilities. Please provide any information that can assist the Department in quantifying these benefits. For purposes of quantifying the benefits of a Web accessibility rule, should the benefits to individuals with cognitive disabilities be treated as one category, or calculated for several separate categories (e.g., learning disabilities, developmental disabilities, neurological disabilities, intellectual disabilities)? If you suggest analyzing different types of cognitive disabilities separately, please explain how the benefits for these groups would differ (e.g., would someone with dyslexia benefit from Web accessibility in ways that someone with a traumatic brain injury would not, and if so, how?) and provide any information that can assist the Department in quantifying benefits for these groups.

For the following question, please note that the Department is seeking this information for the sole purposes of estimating the rule's benefits. The information sought has no bearing on whether an individual with a vision or hearing disability or a manual dexterity limitation is covered under the ADA and in no way limits coverage of these individuals.

Question 62: The Survey of Income and Program Participation classifies people with difficulty seeing, hearing, and grasping into "severe" and "nonsevere" categories, and defines each category. Should the Department's regulatory impact analysis consider differences in disability severity when estimating benefits? Why or why not? If disability severity should be taken into account, are there available studies or data that address time savings for people with different severities of disabilities? If there are no available data or studies addressing this issue, how should estimates of time savings appropriately account for differences in disability severity, if at all?

Question 63: Are there any other disability groups not mentioned above that would benefit from Web accessibility? If so, how would they benefit, and how can these benefits be assigned a monetary value?

b. Benefits of Web Usage

Question 64: What data is available about usage of public entities' Web sites by the general population and by persons with disabilities? For example, what percentage of the population with disabilities and without disabilities accesses public entities' Web sites, and how often do they do so? If barriers to Web site accessibility were removed, would individuals with disabilities use the Internet at the same rate as the general population? Why or why not?

Question 65: To what extent do persons with disabilities choose not to use public entities' Web sites due to accessibility barriers, but obtain information or access services available on these Web sites in another way? Does this vary between disability groups? If so, how and why does it vary?

Question 66: What are the most common reasons for using public entities' Web sites (e.g., to gather information; apply for the public entity's services, programs, or activities; communicate with officials; request services; make payments)?

Question 67: If a person with a disability is using a public entity's Web site and encounters content that is inaccessible, what do they do (e.g., spend longer trying to complete the task online themselves, ask someone they know for assistance, call the entity, visit the entity in person, abandon the attempt to access the information)?

Question 68: How often are persons with disabilities entirely prevented, due to accessibility barriers, from obtaining access to information or services available on public entities' Web sites, including through alternate means (i.e., how often do persons with disabilities never receive information in any form because it is not available on an accessible Web site)? Are there certain services, programs, or activities that public entities only provide online? How would the Department quantify or monetize the information and services not received by people with disabilities because public entities' Web sites are inaccessible?

Question 69: Would more people with disabilities become employed, remain employed, be more productive employees, or get promoted if public entities' Web sites were accessible? If so, what impact would any proposed rule have on the employment rate, productivity, or earnings of people with disabilities? How would the Department quantify or monetize these benefits? Are there other employment-related benefits of Web accessibility for people with disabilities that the Department should consider?

Question 70: Are the educational opportunities available to people with disabilities limited because public entities' Web sites are inaccessible? For example, are the high school or college graduation rates of people with disabilities reduced because public educational institutions' Web sites are inaccessible? Would more people with disabilities graduate high school or college if public educational institutions' Web sites were accessible? If so, what impact would any proposed rule have on the graduation rate of people with disabilities? How would the Department quantify or monetize the value of this increased graduation rate? For example, are there financial benefits that accrue throughout an individual's life as a result of high school or college graduation, and how should these benefits be calculated? Are there other educational benefits of Web accessibility for people with disabilities that the Department should consider?

c. Benefits of WCAG 2.0 Level AA

Question 71: Are there specific provisions of WCAG 2.0 Level AA that are particularly beneficial for individuals with certain types of disabilities (e.g., the requirement for captioning live-audio content in synchronized media provides certain important benefits to individuals with hearing disabilities and auditory processing disorders)? Which provisions provide the most benefits, to whom, and why?

Question 72: Are there specific provisions of WCAG 2.0 Level AA that are difficult or costly to implement? Are there specific provisions of WCAG 2.0 Level AA for which the costs outweigh the accessibility benefits?

d. Benefits to Other Individuals and Entities

Question 73: How would the Department quantify or monetize the resources expended by public entities to assist persons with disabilities by phone or in person? For example, would public entities experience reduced staffing costs due to Web accessibility requirements because fewer staff will be needed to respond to calls or in-person visits from persons with disabilities who will be able to access information via an accessible Web site? How should any reduction in staffing costs be calculated?

Question 74: Are there any additional groups that would benefit from Web accessibility (e.g., individuals without disabilities, senior citizens, caregivers and family members of persons with disabilities)? Please explain how these groups would benefit (e.g., improved navigation enables everyone to find information on Web sites more efficiently, caregivers are able to perform other tasks because the individual with a disability for whom they provide care will need less assistance) and provide any information or data that could assist the Department in quantifying these benefits.

Question 75: Would users without disabilities who currently access a public entity's services via an inaccessible Web site save time if the Web site became accessible (for example, because it is easier to find information on the site once the navigation is clearer)? If so, how much time would they save? Please provide any available data or research to support your responses on the time savings for individuals without disabilities from using accessible Web sites instead of inaccessible Web sites.

2. Time Savings Benefits

The Department is considering monetizing many of the benefits of the Web accessibility rule in terms of time savings—time saved by those current Web users with disabilities who must spend additional time performing tasks because the Web site is not accessible, as well as time saved by those individuals with disabilities who are currently accessing government services via another method but could do so more quickly via an accessible Web site. For example, if a Web site conforms with WCAG 2.0 by providing navigation information in a form that allows screen readers or other assistive technology to retrieve the information, it could take a person with a vision disability less time to locate information on the Web site than it would if the Web site were not accessible. It could also take less time for that individual to access the information on an accessible Web site than it would take them to call the public entity and ask an employee for the same information. The Department has been able to obtain some research on time savings for individuals with vision impairments due to Web accessibility, with one study (prepared in 2004 for the U.K. Disability Rights Commission) finding that users who were blind took approximately 34 percent less time to complete a task on an accessible Web site. U.K. Disability Rights Commission, *The Web: Access and Inclusion for Disabled People* (2004), available at *https://www.city.ac.uk/_data/assets/pdf_file/0004/72670/DRC_Report.pdf* (last visited Apr. 13, 2016). Though this study is helpful for estimating the time savings benefits of Web access regulations, it has some limitations. For example, the study included only people who are blind and people without disabilities, used a small sample size (*i.e.*, it examined 6 Web sites, 12 people who are blind, and 12 people without disabilities), did not detail the types of tasks participants were asked to complete, and was not formally peer reviewed. The Department has also reviewed some research indicating that individuals in general saved over one hour per transaction by completing tasks online. Shari McDaid and Kevin Cullen, *ICT Accessibility and Social Inclusion of People with Disabilities and Older People in Ireland: The Economic and Business Dimensions* (Aug. 18, 2008), available at *http://www.academia.edu/2465494/ICT_accessibility_and_social_inclusion_of_people_with_disabilities_and_older_people_in_Ireland_The_economic_and_business_dimensions* (last visited Apr. 13, 2016). The Department is also considering calculating the potential resources saved by public entities in terms of reduced staff time if many requests for assistance that are currently being made by persons with disabilities by phone or in person instead were handled independently via an accessible Web site.

The Department seeks additional information regarding time savings for users with disabilities, other users, and public entities due to Web site accessibility. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 76: Should the Department evaluate benefits of a Web accessibility rule by considering time savings? Other than those discussed above, are there other studies that can be used to estimate time savings from accessible public entity Web sites? Please provide comments on the appropriate method for using time savings to calculate benefits?

Question 77: Would users with disabilities who currently access a public entity's services by phone or in person save time if they were able to access the public entity's services via an accessible Web site? If so, how much time would they save? Should this time savings be calculated on an annual basis or for a certain number of interactions with the public entity? Please provide any available data or research on time savings from using accessible online services instead of offline methods.

Question 78: Would users with disabilities who currently access a public entity's services via an inaccessible Web site save time if the Web site became accessible? If so, how much time would they save? Would this time savings be limited to users with vision disabilities? If not, is there a difference in the time savings based on type of disability? How would the time savings vary between disability groups (e.g., will individuals with vision disabilities save more time than individuals with manual dexterity disabilities)? Please provide any available data or research to support your responses on time savings for individuals with vision disabilities and other types of disabilities (e.g., hearing disabilities, manual dexterity disabilities, cognitive disabilities, etc.) from using accessible Web sites instead of inaccessible Web sites.

3. Methods of Compliance With Web Accessibility Requirements

As discussed above, generally, the Department is considering proposing that public entities would have two years after the publication of a final rule to make their Web sites and Web content accessible in conformance with WCAG 2.0 Level AA. The Department is also considering whether to allow alternative conformance levels or compliance dates for small public entities or special districts.

The Department seeks information regarding the efforts public entities would need to undertake to comply with a Web accessibility rule, if such a rule were promulgated as framed in this SANPRM. The Department expects that public entities would be able to comply with a Web accessibility rule in several different ways. For example, they might choose to remediate their existing Web site by page or section, or they might instead choose to create a new Web site with accessibility incorporated during its creation. Public entities might choose to use existing staff to perform any needed testing and remediation or hire outside consultants who would do so. The Department seeks information regarding the various options public entities would consider for achieving compliance, and the financial impact of these choices, so that the Department can more precisely estimate the costs of a Web accessibility rule.

In each of your responses, please provide information about how a public entity would comply with WCAG 2.0 Level AA within two years after the publication of a final rule, and explain how your responses would vary if the Department required conformance with WCAG Level A instead of WCAG Level AA, or if the Department allowed additional time for compliance. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 79: How do public entities currently design and maintain their Web sites? Do they use in-house staff or outside contractors, service providers, or consultants? Do they use templates for Web site design, and if so, would these templates comply with a Web accessibility rule? Is there technology, such as templates or software, that could assist public entities in complying with a Web accessibility rule? Please describe this technology and provide information about how much it costs. What are the current costs of Web site design and maintenance? Does the method or cost of Web site design and maintenance vary significantly by size or type of entity?

Question 80: How are public entities likely to comply with any rule the Department issues regarding Web accessibility? Would public entities be more likely to use in-house staff or hire an outside information technology consultant? Would training be required for in-house staff, and if so, what are the costs of any anticipated training? Would the likelihood of using outside contractors and consultants vary significantly by size or type of entity? Would increased demand for outside experts lead to a temporary increase in the costs incurred to hire information technology professionals? If so, how much of an increase, and for how long? Aside from the cost of labor, what are the additional costs, if any, related to the procurement process for hiring an outside consultant or firm to test and remediate a Web site?

Question 81: Are public entities likely to remediate their existing Web site or create a new Web site that complies with the proposed Web accessibility requirements? Does this decision vary significantly by size or type of entity? What are the cost differences between building a new accessible Web site with accessibility incorporated during its creation and remediating an existing Web site? Do those cost differences vary significantly by size or type of entity? Would public entities comply with a Web accessibility rule in other ways?

Question 82: If public entities choose to remediate their existing Web content, is there a cost threshold for the expected costs of accessibility testing and remediation above which it becomes more cost effective or otherwise more beneficial for an entity to build a new Web site instead of remediating an existing one? If so, what is that cost threshold? How likely are entities of various types and sizes to cross this threshold?

Question 83: Would public entities choose to remove existing Web content or refrain from posting new Web content instead of remediating the content to comply with a Web accessibility rule? How would public entities decide whether to remove or refrain from posting Web content instead of remediating the content? Are public entities more likely to remove or refrain from posting certain types of content? Is there a cost threshold above which entities are likely to remove or refrain from posting Web content instead of remediating the content? If so, what is that cost threshold?

Question 84: In the absence of a Web accessibility rule, how often do public entities redesign their Web sites? Do they usually redesign their entire Web site or just sections (e.g., the most frequently used sections, sections of the Web site that are more interactive)? What are the benefits of Web site redesign? What are the costs to redesign a Web site? If a Web site is redesigned with accessibility incorporated, how much of the costs of the redesign are due to incorporating accessibility?

4. Assessing Compliance Costs

The Department is attempting to estimate the costs a public entity would incur to make and maintain an accessible Web site in conformance with the technical standard under consideration by the Department. Several governmental entities in the

U.S. and abroad have already undertaken efforts to estimate the likely costs of requiring that Web sites meet certain accessibility standards. A Preliminary Regulatory Analysis of a proposed rule regarding accessible kiosks and Web sites of air carriers prepared for the U.S. Department of Transportation sought to estimate the costs to carriers using a per-page methodology. U.S. Department of Transportation, *Nondiscrimination on the Basis of Disability in Air Travel: Accessibility of Web sites and Automated Kiosks at U.S. Airports, Preliminary Regulatory Analysis* (Sept. 19, 2011), available at *http://www.regulations.gov/#!documentDetail;D=DOT-OST-2011-0177-0002* (last visited Apr. 13, 2016). A per-page methodology is a methodology that multiplies the number of pages on a Web site by an established cost value. The Final Regulatory Analysis prepared for that rule took a different approach and derived estimates for three size categories of carriers based on comments to the Preliminary Regulatory Analysis. U.S. Department of Transportation, *Nondiscrimination on the Basis of Disability in Air Travel: Accessibility of Web sites and Automated Kiosks at U.S. Airports, Final Regulatory Analysis on the Final Rule on Accessible Kiosks and Web sites* (Nov. 4, 2013), available at *http://www.regulations.gov/#!documentDetail;D=DOT-OST-2011-0177-0108* (last visited Apr. 13, 2016). In 2012, the European Commission sponsored a study to quantify evidence on the socioeconomic impact of Web accessibility. Technosite *et al., Study on Economic Assessment for Improving e-Accessibility Services and Products,* (2012) available at *http://www.eaccessibility-impacts.eu/* (last visited Apr. 13, 2016). That report used a level of effort approach, in which costs were estimated based on an average number of hours needed to remediate a typical Web site in several specified size groupings. *Id.*

At present, the Department is considering three different approaches for estimating costs. The first is a per-page methodology that multiplies the average number of pages on a Web site by an established testing, remediation, or operation and maintenance cost per page (and possibly by type of page). The second approach under consideration is a level of effort methodology, which would estimate costs based on Web site size groupings or size 'bins' (such as less than 100 pages, 100 to 500 pages, etc.). The third potential approach would combine the per-page and level of effort methodologies. The Department will also consider other feasible approaches to estimating costs that are proposed.

The Department seeks public comment on these potential methodologies, any alternative methodologies for estimating compliance costs that the Department should consider, and the appropriate input values that the Department should use for testing, remediation, and operation and maintenance if it chose one of these methodologies. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 85: Should the Department estimate testing, remediation, and operation and maintenance costs on a cost-per-page basis? If so, how should the average cost per page be determined for testing, remediation, and operation and maintenance? How should these costs be calculated? Should different per-page estimates be used for entities of different sizes or types, and if so how would they vary? Should different per-page cost estimates be used for different types of page content (text, images, live or prerecorded synchronized media) or for static and dynamic content? If you propose using different per-page cost estimates for different types of content, what are the appropriate types of content that should be used to estimate costs (e.g., text, images, synchronized media (live or prerecorded), forms, static content, dynamic content), how much content should be allocated to each category, and what are the appropriate time and cost estimates for remediation of each category?

Question 86: If the Department were to use a cost-per-page methodology, how would the average number of pages per Web site be determined? Should the Department seek to estimate Web site size by sampling a set number of public entities and estimating the number of pages on those Web sites? When presenting costs for different categories of Web sites by size, how should Web sites be categorized (i.e., what should be considered a small, medium, or large Web site)? Should Web site size be discussed in terms of the number of pages, or is there a different metric that should be used to discuss size?

Question 87: If a level of effort methodology is used, what are the appropriate Web site size categories that should be used to estimate costs and what are the different categories of Web elements for which remediation time should be estimated (e.g., informative, interactive, transactional, multimedia)? What are appropriate time estimates for remediation for each category of Web elements? What wage rates should be used to monetize the time (e.g., government staff, private contractor, other)?

Question 88: Do the testing, remediation, and operation and maintenance costs vary depending on whether compliance with WCAG 2.0 Level A or Level AA is required, and if so, how?

Question 89: What other methods could the Department use to estimate the costs to public entities of compliance? Which methodology would allow the Department to estimate most accurately the entities' costs for making their Web sites accessible?

5. Indirect Costs Associated With Compliance

The Department is also attempting to ascertain whether there are other types of compliance costs associated with the Web accessibility rule presently under consideration, such as the cost of "down time," systems change, regulatory familiarization costs, or administrative costs. Regulatory familiarization and other administrative costs include the time a public entity spends evaluating and understanding the requirements of the rule and determining how to comply with those requirements, and time which might be needed for making or adjusting short- and long-term plans and strategies and assessing the public entity's resources. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 90: If public entities remediate their Web sites to comply with a Web accessibility rule, would they do so in such a way that accessible Web pages are created and tested before the original Web pages are removed, such that there is no "down time" during the upgrade? If not, how much "down time" would occur, and what are the associated costs?

Question 91: Would public entities incur additional costs related to modifying their current methods for processing online transactions if those are inaccessible due to applications or software currently used? If so, what are these costs, and how many public entities would incur them?

Question 92: Would there be additional indirect administrative costs associated with compliance with a Web accessibility rule, and if so, what are these costs?

Question 93: Would there be any costs related to familiarization with the new regulations, and if so, what are these costs? How much time would be needed for regulatory familiarization, and how much would this cost?

Question 94: Are there other considerations the Department should take into account when evaluating the time and cost required for compliance with a Web accessibility rule, and if so, what are these costs?

6. Current Levels of Accessibility for Public Entity Web Sites

The benefits and costs of proposed regulations are commonly defined relative to a no-action baseline that reflects what the world would look like if the proposed rule is not adopted. In the case of a Web accessibility rule, the no-action baseline should reflect the extent to which public entities' Web sites would comply with accessibility requirements even in the absence of the proposed rule. In an attempt to establish this baseline, the Department considered studies regarding existing public entity Web site accessibility; the extent to which some public entities have adopted statutes or policies that require their Web sites to conform to accessibility requirements under section 508 of the Rehabilitation Act, WCAG 1.0, or WCAG 2.0; and the extent to which some public entities' Web sites have been made accessible due to settlement agreements with the Department of Justice, other agencies, or disability advocacy groups, and publicity surrounding these enforcement efforts. Based on this research, the Department is considering evaluating the benefits and costs of a Web accessibility rule relative to a no-action baseline that assumes that some percentage of Web sites are already accessible and that some percentage of pages on other Web sites are accessible, and therefore either would not incur testing or remediation costs at all, or would only incur these costs for a portion of the Web site.

Question 95: Which public entities have statutes and/or policies that require or encourage their Web sites to be accessible to persons with disabilities and/or to conform to accessibility requirements under section 508, WCAG 1.0, and/or WCAG 2.0? Do these laws and/or policies require (not just suggest) conformance with a particular Web accessibility standard, and if so, which one? Are these laws and/or policies being implemented, and, if so, are they being implemented at just the State level of government or at the local levels as well? The Department asks that the public provide additional information on current State or local policies on Web accessibility, including links or copies of requirements or policies, when possible.

Question 96: What percentage of public entities' Web sites and Web pages are already compliant with Web accessibility standards, or have plans to become compliant even in the absence of a Web accessibility rule? What would be a reasonable "no-action" baseline accessibility assumption (i.e., what percentage of Web sites and Web pages should the Department assume are already compliant with Web accessibility standards or will be even in the absence of a rule)? Should this assumption be different for different sizes or types of public entities (e.g., should a different percentage be used for small public entities)? Please provide as much information as possible to support your response, including specific data or research where possible.

Question 97: If State or local entities already comply with WCAG 2.0, what were the costs associated with compliance? Please provide as much information as possible to support your response, including specific data where possible.

7. Public Entity Resources

In an attempt to evaluate the impact of a Web accessibility rule on public entities, the Department may consider publicly reported information about the annual revenues of public entities with different population sizes. Because this information is necessarily reported in the aggregate, it provides a limited view of the resources available to individual public entities for specific purposes, since many funds are targeted or restricted for certain uses. The Department is therefore seeking additional, specific information from public entities that explains, in detail, the impact of a proposed Web accessibility rule like the proposal currently under consideration by the Department, based on public entities' available resources. This information will enable the Department to strike an appropriate balance between access for individuals with disabilities and burdens on public entities when fashioning a proposed rule. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 98: Is the Department correct to evaluate the resources of public entities by examining their annual revenue? Is annual revenue an effective measure of the potential burdens a Web accessibility rule could impose on public entities? Is there other publicly available data that the Department should consider in addition to, or instead of, annual revenue when considering the burdens on public entities to comply with a Web accessibility rule?

Question 99: Are there resources that a public entity would need to comply with a Web accessibility rule that they would not be able to purchase (e.g., staff or contractors with expertise that are not available in the geographic area)? Are there other constraints on public entities' ability to comply with a Web accessibility rule that the Department should consider?

8. Compliance Limitations

The Department is considering proposing that, as with other ADA requirements, compliance with any technical Web accessibility standard the Department adopts would not be required to the extent that such compliance imposes undue financial and administrative burdens, or results in a fundamental alteration of the services, programs, or activities of the public entity. When compliance with the applicable standard would be an undue burden or fundamental alteration, a covered entity would still be required to provide effective communication or reasonable modifications to individuals with disabilities through other means upon request (*e.g.*, via telephone assistance), unless such other means constitute an undue burden or fundamental alteration.

The Department seeks additional information about how these compliance limitations would apply, as well as proposals for less burdensome alternatives to consider. The data that commenters provide to help answer these questions should be well supported and explain whether public entities could comply to some extent with the Web accessibility requirements. It should also explain what provisions of the proposed requirements, if any, would result in undue burdens for certain public entities, and why. In each of your responses, please assume that the proposed rule would require compliance with WCAG 2.0 Level AA within two years after the publication of a final rule, and explain how your responses would vary if the Department required conformance with WCAG Level A instead of WCAG Level AA, or if the Department allowed additional time for compliance. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 100: Are there any other effective and reasonably feasible alternatives to making the Web sites of public entities accessible that the Department should consider? If so, please provide as much detail as possible about these alternatives in your *answer, including information regarding their costs and effectiveness.*

9. Conventional Electronic Documents

In order to assess the potential costs of making conventional electronic documents accessible, the Department would like to know, on average, how many conventional electronic documents are currently on public entities' Web sites, and, on average, what percentage of these documents is being used to apply for, gain access to, or participate in a public entity's services, programs, or activities. In addition, the Department would like to know, on average, how many new conventional electronic documents are placed on public entities' Web sites annually, and whether additional compliance costs (beyond staff time) would be needed to make new documents accessible after the compliance date. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 101: How many conventional electronic documents currently exist on public entities' Web sites? What is the purpose of these conventional electronic documents (e.g., educational, informational, news, entertainment)? What percentage of these documents, on average, is used to apply for, gain access to, or participate in the public entity's services, programs, or activities?

Question 102: How many new conventional electronic documents are added to public entities' Web sites, on average, each year and how many, on average, are updated each year? Will the number of documents added or updated each year change over time?

Question 103: What are the costs associated with remediating existing conventional electronic documents? How should these costs be calculated? Do these costs vary by document type, and if so, how? Would these costs vary if compliance with WCAG 2.0 Level A was required instead of compliance with WCAG 2.0 Level AA, and if so, how?

Question 104: What costs do public entities anticipate incurring to ensure that the conventional electronic documents placed on their Web sites after the compliance date of any Web accessibility rule are accessible (e.g., will they be created with accessibility built in, or will they need to be remediated)? Would public entities use any specific type of software to ensure accessibility? What is the cost of this software, including the costs of any licenses? What kind of training about accessible conventional electronic documents would be needed, if any, and what would the training cost? How many hours per year would it take public entities to ensure that the conventional electronic documents posted on their Web sites are accessible after the compliance date of any Web accessibility rule?

10. Captioning and Audio Description

WCAG 2.0 Level AA Success Criteria require captions for all recorded-audio and live-audio content in synchronized media, as well as audio description. Synchronized media refers to "audio or video synchronized with another format for presenting information and/or with time-based interactive components. . . ." *See* W3C®, *Understanding WCAG 2.0: Understanding Guideline 1.2,* (Feb. 2015) available at *http://www.w3.org/TR/UNDERSTANDING-WCAG20/media-equiv.html* (last visited Apr. 13, 2016). A common example of synchronized media is a video clip that presents both audio and video together. At present, little information exists regarding the current quantities of synchronized media on public entities' Web sites or their size or length. The Department has been able to collect data on the average cost of captioning audio content or audio describing video content (mostly on a per-hour or per-minute basis), but data to estimate which public entities might incur these costs and the amount of these costs were not found. The fact that some recorded and live media on public entities' Web sites are also being broadcast on public access channels by the public entity and, thus, might already be captioned or audio described further complicates the Department's ability to collect detailed estimates of the costs of captioning and audio description. Thus, the Department seeks specific information that will enable it to more precisely estimate the costs public entities would incur if requirements for captioning and audio description were proposed. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 105: How much synchronized media (live or prerecorded) is available on public entities' Web sites? How much of this synchronized media is live (i.e., streaming) and how much is prerecorded? What is the running time of such media? What portion of the media contains speech, and how much speech does it contain? What is the purpose of the synchronized media (e.g., educational, informational, civic participation, news, entertainment)?

Question 106: How often do individuals with vision or hearing disabilities attempt to access synchronized media on public entities' Web sites? How much of the synchronized media that individuals with vision or hearing disabilities attempt to access is live and how much is prerecorded? What is the purpose of attempting to access this synchronized media (e.g., educational, informational, civic participation, news, entertainment)? What percentage of the synchronized media is not captioned or audio described, and what portion of the media that is not captioned or audio described is live versus prerecorded?

Question 107: What do individuals with vision or hearing disabilities do when synchronized media is not captioned or audio described? Do they spend additional time seeking the information or content in other ways (e.g., do they need to make a phone call and remain on hold)? If so, how much additional time do they spend trying to obtain it? How do they actually obtain this information or content? How much additional time, other than the individual's own time spent seeking the information, does it take to obtain the information or content (e.g., does it take several days after their request for the information to arrive in the mail)?

Question 108: To what extent do persons with vision or hearing disabilities refrain from using public entities' Web sites due to a lack of captioning or audio description? Would persons with vision or hearing disabilities use public entities' Web sites more frequently if content were captioned or audio described? To what extent does the lack of captioning or audio description make using public entities' Web sites more difficult and/or time consuming?

Question 109: Would people with cognitive or other disabilities benefit from captioning or audio description of synchronized media on public entities' Web sites? If so, how, and how can a monetary value be assigned to these benefits?

Question 110: Currently, what are the specific costs associated with captioning prerecorded and live-audio content in synchronized media, including the costs of hiring professionals to perform the captioning, the costs associated with the technology, and other components involved with the captioning process? Aside from inflation, are these costs expected to change over time? If so, why will they change, when will they begin to do so, and by how much?

Question 111: Currently, how much synchronized media content are public entities providing that would need to be *audio described due to the presence of important visual aspects that would not be conveyed via sound? What types of content on public entities' Web sites would need to be audio described?*

Question 112: Currently, what are the specific costs associated with audio describing content in synchronized media, including the costs of hiring professionals to perform the description, the costs associated with the technology, and other components involved with the audio description process? Aside from inflation, are these costs expected to change over time? If so, why will they change, when will they begin to do so, and by how much?

11. Public Educational Institutions

The Department is considering whether public educational institutions (*i.e.*, public elementary and secondary schools and public postsecondary institutions) may face unique challenges in complying with a Web accessibility rule. Public educational institutions' Web sites may be more complex and interactive than other public entities' Web sites, primarily because of the characteristics of online education and the use of LMSs. Many aspects of public educational institutions' Web sites are accessed via a secure Web portal. The secured portions of public educational institutions' Web sites may require more regular access and interaction for completing essential tasks such as course registration and course participation. Because these portions of the Web sites require individualized usernames and passwords, the Department has been unable to evaluate the characteristics of these Web sites to date, thus making it difficult to monetize the benefits and costs of making the secured portions of the Web sites accessible in accordance with the proposal currently under consideration by the Department. The Department seeks additional information regarding the benefits and costs of Web accessibility for public educational institutions. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 113: Do public educational institutions face additional or different costs associated with making their Web sites accessible due to the specialized nature of the software used to facilitate online education, or for other reasons? If so, please describe these additional costs, and discuss how they are likely to be apportioned between public educational institutions, consumers, and software developers.

Question 114: How should the monetary value of the benefits and costs of making the secured portions of public educational institutions' Web sites accessible be measured? What methodology should the Department use to calculate these benefits and costs?

Question 115: Is there a cost threshold for the expected costs of accessibility testing and remediation above which it becomes more cost effective or otherwise more beneficial for a public educational institution to build a new Web site instead of remediating an existing one? If so, what is that cost threshold for each type of public educational institution (e.g., public elementary school, public secondary school, public school district, public postsecondary institution)? How likely is each type of public educational institution to cross this threshold?

12. Impact on Small Entities

Consistent with the Regulatory Flexibility Act of 1980 and Executive Order 13272, the Department must consider the impacts of any proposed rule on small entities, including small governmental jurisdictions ("small public entities"). *See* 5 U.S.C. 603–04 (2006); E.O. 13272, 67 FR 53461 (Aug. 13, 2002). At the next rulemaking stage, the Department will make an initial determination as to whether any rule it proposes is likely to have a significant economic impact on a substantial number of small public entities. If so, the Department will prepare an initial regulatory flexibility analysis analyzing the economic impacts on small public entities and the regulatory alternatives the Department considered to reduce the regulatory burden on small public entities while achieving the goals of the regulation. At this stage, the Department seeks information on the potential impact of a Web accessibility rule on small public entities (*i.e.*, governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000) to assist it to more precisely conduct an initial regulatory flexibility analysis at the next rulemaking stage.

The Department recognizes that small public entities may face resource constraints that could make compliance with some Web accessibility standards difficult. The Department therefore seeks additional, specific information regarding these constraints. The Department encourages small public entities to provide cost data on the potential economic impact of adopting the specific requirements for Web site accessibility under consideration by the Department. The Department also encourages small public entities to provide recommendations on less burdensome alternatives, with relevant cost information. The Department also seeks additional information that will enable it to quantify the benefits of any such rule for individuals with disabilities residing in small public entities. For example, individuals with manual dexterity limitations residing in small public entities may find Web accessibility more important than individuals with similar disabilities residing in larger public entities that may have more accessible public transportation and greater physical accessibility. However, it is also possible that Web accessibility is less important for individuals with manual dexterity limitations residing in small public entities because they do not need to travel very far to access government services in-person, or very little information is available on their town's Web site. In each of your responses, please assume that the proposed rule would require compliance with WCAG 2.0 Level AA within two years after the publication of a final rule, and explain how your responses would vary if the Department required conformance with WCAG Level A instead of WCAG Level AA, or if the Department allowed additional time for compliance. Please include as much information as possible to support each of your responses, including specific data or research where possible.

Question 116: Do all or most small public entities have Web sites? Is there a certain population threshold below which a public entity is unlikely to have a Web site?

Question 117: How large and complex are small public entities' Web sites? How, if at all, do the Web sites of small public entities differ from Web sites of larger public entities? Do small public entities tend to have Web sites with fewer pages? Do small public entities tend to have Web sites that are less complex? Are small public entities less likely to provide information about or access to government services, programs, and activities on their Web sites? Do the Web sites of small public entities allow residents to access government services online (e.g., filling out forms, paying bills, requesting services)?

Question 118: Are persons with disabilities residing in small public entities more or less likely to use the public entities' Web sites to access government services? Why or why not?

Question 119: Is annual revenue an effective measure of the potential burdens a Web accessibility rule could impose on small public entities? Is there other publicly available data that the Department should consider in addition to, or instead of, annual revenue when considering the burdens on small public *entities to comply with a Web accessibility rule?*

Question 120: Are there resources that a small public entity would need to comply with a Web accessibility rule that they would not be able to purchase (e.g., staff or contractors with expertise that are not available in the geographic area)?

Question 121: Do small public entities face particular obstacles to compliance due to their size (e.g., limited revenue, small technology staff, limited technological expertise)? Do small public entities of different sizes and different types face different obstacles? Are there other constraints on small public entities' ability to comply with a Web accessibility rule that the Department should consider?

Question 122: Are small public entities likely to determine that compliance with a Web accessibility rule would result in undue financial and administrative burdens or a fundamental alteration of the services, programs, or activities of the public entity? If so, why would these compliance limitations result?

Question 123: Are there alternatives that the Department could consider adopting that were not previously discussed that could alleviate the potential burden on small public entities? Please provide as much detail as possible in your response.

Dated: April 29, 2016.

Vanita Gupta,

Principal Deputy Assistant Attorney General, Civil Rights Division.

[FR Doc. 2016–10464 Filed 5–6–16; 8:45 am]

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